WHO compendium of innovative health technologies for low-resource settings

2024

World Health Organization

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Preface

Portrait of Dr Yukiko Nakatani, Geneva, Switzerland 2024
Credit: WHO / Pierre Albouy

The WHO Compendium of Innovative Health Technologies for Low-resource Settings (the Compendium) published in 2011 was the first in which technologies tailored to those contexts were identified. Periodic calls for submissions have resulted in compilation and publication of seven volumes, addressing various health challenges. The focus of the current, eighth volume was primarily noncommunicable diseases (NCDs), although technologies for other health priorities are also included. Cardiovascular diseases, cancers and chronic respiratory diseases are the causes of 74% of NCD-related deaths globally. In low- and middle-income countries (LMIC), and 86% of all deaths and over 75% of the 17 million premature deaths (before the age of 70) are due to NCDs. Stakeholders in low-resource settings, however, often have difficulty in identifying appropriate solutions *(1).*

The series of Compendium volumes cover a wide range of health technologies for health priorities in low-resource settings. From medical devices and e-health solutions to assistive devices, laboratory equipment and technologies for outbreaks, each edition has proposed innovative solutions to address current health challenges. For instance, the 2016–2017 edition included personal protective equipment for haemorrhagic fevers in tropical climates in response to the outbreak of Ebola virus disease, and the volumes issued in 2021 and 2022 focused on health technologies for the COVID-19 response and other health priorities.

Several improvements have been made to the method and format of the Compendium. With the support of the Strategic Advisory Group on Medical Devices and Health Technologies (STAG MEDEV) *(2),* the method has been refined to ensure a robust assessment of each technology. This involved revising indicators, enhancing data collection tools, and linking submission requirements directly to evaluation criteria. The result is a more comprehensive, evidence-based assessment.

Furthermore, the format of the Compendium has been changed to provide stakeholders with a detailed description of each technology. The first Compendium included a one-page summary of each health problem addressed, the proposed solution and specifications. In this edition, readers are provided with comprehensive three-page reports that include details of the technology submitted by the innovator and the results of the WHO assessment, which includes reference to clinical aspects, technical specifications, regulatory compliance, health technology assessments (HTAs), health technology management (HTM), intellectual property and local production. These improvements are expected not only to increase awareness of innovative health technologies but also to facilitate their adoption and implementation in low-resource settings. By providing evidence-based assessments, we empower decision-makers to make informed choices that will ultimately improve health outcomes and enhance health-care delivery. Additional information on all editions of the Compendium is available at https://www.who.int/activities/accelerating-impact-for-innovations-for-health.

WHO invites policymakers, biomedical and clinical engineers, clinicians, technology developers, donors, and other stakeholders to use this volume of the Compendium and join us in accelerating the impact of innovations for health specially in low-resource settings.

Yukiko. N

Dr Yukiko Nakatani
Assistant Director-General
Access to Medicines and Health Products

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Declaration of interests

The WHO secretariat collected, managed and reviewed the declarations of interests (DOIs) submitted and signed by the STAG MEDEV members, and all experts, reviewers, and consultants commissioned by WHO prior to commencing their work, and found no STAG MEDEV members, experts, reviewers, and consultants to have a potential conflict of interest.

Abbreviations

CE	Conformité Européenne
CER	clinical evaluation report
CFR	Code of Federal Regulations
EDL	essential diagnostics list
EMC	electro-magnetic compatibility
EU	European Union
GMP	good manufacturing practice
GNI	gross national income
HFNC	high flow nasal cannula
hPA	hectopascal
HTA	health technology assessment
HTM	health technology management
IMDRF	International Medical Device Regulators Forum
IP	intellectual property
ISO	International Standards Organization
IVD	in vitro diagnostic medical device
IVDR	In Vitro Diagnostic Medical Device regulation (Europe)
LMIC	low- and middle-income countries
LRS	low resource setting
mAh	mili ampere-hour
MDA	medical device authority
MDD	Medical Device Directive (Europe)
MDR	Medical Device Regulation (Europe)
ME	medical electrical
NCD	noncommunicable disease
RDR	rapid diagnostic reader
RH	relative humidity
RDT	rapid diagnostic test
SoC	standard of care
STAG MEDEV	Strategic and Technical Advisory Group on Medical Devices
USFDA	United States Food and Drug Administration
VAC	volts alternating current

Glossary

510(k) boundary condition: The elements of a device cleared by US Food and Drug Administration (USFDA) 510(k) that establish the characteristics of the device and demonstrate substantial equivalence, including descriptions, predicate comparisons, labelling, performance characteristics and evaluation criteria.

510(k) clearance: A notification submitted to the USFDA to conform to section 510(k) of the US Food, Drug and Cosmetic Act that demonstrates that a medical device intended to be marketed in the United States of America (USA) is "substantially equivalent" to a legally marketed device. Submissions can be classified as traditional, abbreviated or special, depending on whether the device has been modified, is new or is already on the market. Clearance is granted to devices that receive marketing authorization from the USFDA. The process does not constitute approval.

Biocompatibility: In general, refers to the property of a material that makes it compatible with living tissue. When biocompatible materials are exposed to a body or body fluids, they do not produce a toxic or immunological response. International Standards Organization (ISO) 10993 is the globally recognized standard for the biocompatibility of all medical devices. Many other standards address specific aspects of biocompatibility testing and/or the biocompatibility of medical devices.

Biomedical engineering: A field of practice of engineering that considers the physiology and structures of the human body, to support the development of medical devices for prevention, diagnosis and treatment of disease and modifying or supplementing the anatomy of the body. Biomedical engineering is considered as the profession responsible for innovation, research and development, design, selection, management, and safe use of all types of medical devices, including single-use and reusable medical equipment, prosthetics, implantable devices, and bionics, among others. Biomedical engineering includes equivalent or specialized disciplines, whose names might be different in diverse countries, such as medical engineering, electromedicine, bioengineering, medical and biological engineering, and clinical engineering *(3)*.

Certificate to Foreign Government: A USFDA certificate required by some countries to prove that an exported medical device exported from the USA is legally marketed and in compliance with the requirements of the US Food, Drug, and Cosmetic Act.

Clinical evaluation report (CER): A document that contains the findings of a clinical evaluation of a medical device. A CER comprises analysed clinical data that were obtained in a clinical investigation of a device or in studies of devices that are substantially equivalent. A CER demonstrates that a device fulfills its intended purpose without exposing users or patients to additional harm. The European Union's MEDical DEVices document, MEDDEV 2.7/1 revision 4, and the Medical Device Regulation provide manufacturers with guidance on proper evaluation of the clinical safety and performance of devices.

Clinical outcome: Measurable change in health or quality of life as result of specific health–care interventions

Conformité Européenne (European Conformity) (CE):. A mandatory European mark for products (including medical devices) to indicate conformity with essential health and safety requirements set out in EU directives and regulations.

Field safety corrective action: An action taken by a manufacturer to reduce the risk of death or serious deterioration in the state of health associated with use of a device that is already on the market. The manufacturer must plan a specific course of action to be taken for a specific recall, whether a public warning is necessary and the extent of checks for a recall. A recall is part of a post-marketing risk assessment to ensure continued safe use of a medical device and is an important part of post-market surveillance. All medical device manufacturers shall comply with all requirements relating to mandatory reporting of problems to continuously ensure the safety and performance of medical devices that have been placed on the market.

Good manufacturing practice (GMP): The requirements for ensuring the quality of USFDA-regulated products. GMP for medical devices is described in 21 Code of Federal Regulations, CFR 820 (see Quality system regulation) *(4)*.

Health innovation: For this publication, a technology is deemed to be innovative when it is deemed to be safer, more effective, more acceptable, more appropriate, more organizationally resilient, more equitable, more economically viable or greener in low-resource settings.

Health technology: Defined by WHO as application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems that have been developed to solve a health problem and improve the quality of life *(5)*.

Health technology assessment (HTA): A multidisciplinary process in which specific methods are used to determine the value of a health technology in comparison with others at various times in its lifecycle. Used in making decisions to ensure an equitable, efficient, high-quality health system *(6)*.

Health technology management (HTM): management of health-related devices and their use in clinical procedures and systems, typically accomplished by clinical engineers or biomedical engineers who serve at the point of care.

IEC 60601-1-2:2014: Documentation of the results of electromagnetic compatibility tests is based on this standard. Such testing is crucial for medical devices to ensure proper functioning in an electromagnetic environment and to minimize the risk of electromagnetic interference with other devices.

Instructions for use: A document required for medical products to communicate instructions for safe operation and application of medical products.

ISO 14971 – Medical devices: An international standard that specifies the process to be used by a manufacturer to identify the hazards associated with medical devices, to estimate and evaluate the associated risks, control those risks and monitor the effectiveness of the controls.

ISO 13485 – Medical devices: An international standard that specifies the requirements for a quality management system to be used by manufacturers, distributors and others involved in medical devices at any time in their lifecycle. Organizations must adhere to this standard to demonstrate that they can provide medical devices and related services that consistently meet customers' and applicable regulatory requirements.

Label: Any display of written, printed or graphic matter on or affixed to the immediate container or package of any article.

Labelling: All written, printed or graphic matter that accompanies an article at any time while the article is in interstate commerce or held for sale after shipment in interstate commerce. It includes user manuals, instructions for use, brochures, advertising, websites and verbal communications.

Lifecycle of equipment at a health facility: The steps taken during the lifecycle of equipment are selection, set-up, use, decontamination, preventive maintenance, corrective maintenance and decommissioning *(7)*.

Lifecycle of health technology: Period from the idea and the conceptualization of a medical device and its eventual commercialization, clinical application, upgrade, allocation and retirement.

Low- and middle-income countries (LMIC): As defined by the World Bank, low-income economies are those with a gross national income (GNI) per capita of ≤ US$ 1135 in 2022; lower–middle-income economies are those with a GNI per capita of US$ 1136–4465; and upper–middle-income economies are those with a GNI per capita of US$ 4466–13 845 *(8)*.

Low-resource setting: Any place with limited infrastructure (e.g. no running water, unstable or unavailable electricity, few or no specialized health professionals, poor accessibility).

Maintenance: A set of activities (including repair, planned, preventive and/or predictive maintenance) to sustain the availability of safe, calibrated, patient-ready products.

Manufacturer: An entity in which a (medical) product is built manually or mechanically and for which it is legally responsible.

Medical device: International Medical Device Regulators Forum IMDRF/GHTF/SG1/N071:2012 defines a medical device as any instrument, apparatus, appliance, software, implant, reagent, material or other item intended by a manufacturer to be used alone or in combination for human beings for one or more of the following specific medical purposes: diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability; investigation, replacement or modification of the anatomy or of a physiological or pathological process or state *(5)*; or providing information by in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

Medical Device Directive (MDD): Legislation (Council Directive 93/42/EEC) that sets general requirements for the design and construction of medical devices and their accessories, excluding in vitro and active implantable devices. Provides the legislative framework within which Competent Authorities and Notified Bodies of Member States of the EU and the European Free Trade Association regulate CE marking for placing and maintaining medical devices on the market in the EU.

Medical device regulation: In Europe, regulation (EU) 2017/745 in the EU and the European Free Trade Association will replace the MDD. The new rules apply to all medical devices on the market since May 2021.

Performance evaluation report: A report on assessment and analysis of data to establish or verify the performance of an IVD medical device. CER equivalent requirement for EU IVDs.

Periodic safety update report: In Europe, a report that summarizes the results and conclusions of analyses of data collected within a post-market surveillance plan, with a rationale and description of any preventive and corrective actions taken, throughout the lifetime of a device. Required for EU MDR classes IIa, IIb and III and for in vitro diagnostic medical device regulation (IVDR) classes C and D devices.

Point of care: A location, usually in a health-care setting, where patients and providers interact. Technology is often used in such interactions.

Post-market surveillance: Manufacturers and economic operators participate in proactive, systematic collection and review of experience with marketed products. This global regulatory and quality assurance system is required to monitor the safety and effectiveness of a product after it has been placed on the market. The USFDA defines post-marketing surveillance as including tracking systems; reporting of device malfunctions, serious injuries or deaths; registering the establishments in which devices are produced or distributed; post-market surveillance studies; and post-approval studies.

Post-market surveillance report: In Europe, required for EU MDR Class I and IVDR Class A and B devices.

Quality system regulation 21 CFR 820: The US federal regulation that specifies the good manufacturing practices to be used by medical device companies. Manufacturers must establish and follow quality system regulation to ensure that their products consistently meet applicable requirements and specifications.

Repair: Activities performed at the demand of qualified individuals to restore a medical product to its original performance and condition.

Risk management: Systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk.

Robustness: The quality of resilience or the ability to withstand adverse conditions.

Software validation: Evaluation of software during or at the end of its development to determine whether it satisfies specified business requirements.

Spare part: Component used to replace a defective original component of a product.

Survey: Activities to generate new knowledge with a tool for data collection.

Technology readiness level (TRL): Estimate of the maturity of a technology on a scale of 1 to 9, 9 being the most mature technology *(9)*. The TRL evaluation in the Compendium is based on specific development, testing, and market milestones adoption of the product, and the assigned readiness level is determined by the evidence provided by the manufacturer. For example, a CE mark commercial device can be TRL 9. Conversely, a prototype that has been successfully tested under operational conditions and has not yet been certified might be TRL7. Other evidence, provided by the innovator, helps to classify the technology at intermediate readiness levels.

- TRL 1-4 – including needs assessment, concept development of a working prototype, bench and animal testing. Proof of concept established.
- TRL 5-6 – small scale pilot and feasibility testing conducted on prototypes/proof of concept.
- TRL 7-8 – large-scale testing leading to regulatory approval and further evidence generation.
- TRL 9 – market access, adoption and post-market surveillance.

Terms, conditions and disclaimers

Disclaimer to the call

WHO reserves the right not to select any application or to annul the solicitation process at any time without incurring any liability or any obligation to inform the applicants of the grounds for WHO's action. WHO reserves the right, at any time during the solicitation process, to modify the scope of the call. At any step in the evaluation process, WHO reserves the right to issue an amendment to the call detailing the change to only those applicants who have not been officially eliminated at that point in time. Applications will be evaluated by WHO, in collaboration with partner experts and institutions, at its sole discretion, taking into account the criteria outlined above. There is no obligation by WHO to reveal or discuss with any applicant how a submission was assessed or to provide any other information relative to the selection process.

Incomplete applications and applications submitted after the deadline will, in principle, be disregarded unless WHO, at its sole discretion, decides otherwise in respect of such incomplete or late application. WHO may request applicants to submit complementary or additional information as a condition for consideration. Any possible requests to submit complementary information and/or a more detailed application, as well as any discussions ensuing therefrom, will be exploratory only, and do not mean that the applicant concerned will be selected.

WHO will not be held to offer applicants any explanation or justification as to why their proposal has been rejected and/or why they have not been selected. The list of selected applications will not necessarily be made public. The submission of applications, the subsequent selection process, and the outcome of the selection process will not be subject to any claim of any kind whatsoever or appeal. Each applicant will be notified by WHO in writing (by e-mail) whether or not their submission has been selected.

Any and all costs and expenses incurred in relation to, or ensuing from, the submission of an application (including the possible request by WHO for complementary information and/or a more detailed proposal) will not be subject to claims for financial compensation of any kind whatsoever.

WHO does not warrant that any medical devices, innovations, concepts, or products that may be used, identified, or otherwise developed from selected proposals will be successfully commercialized in target countries, or that WHO will finance or otherwise support the development or commercialization of any product. By selecting applications, WHO will not be held to endorse any product but will solely aim to draw stakeholders' attention to innovative technologies with a view to furthering the development and availability of and access to such innovative health technologies.

The mention of specific companies or certain manufacturers' products at any stage of the selection process or subsequently will not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned, nor that they have been found to be safe and efficacious.

Without WHO's prior written approval, selected applicants shall not, in any statement of an advertising or promotional nature, refer to their selection under this call for innovative health technologies. In no case shall selected applicants use the name or emblem of the World Health Organization, or any abbreviation thereof, in relation to their business or otherwise. The same applies to all applicants during the selection process and thereafter.

Disclaimer for the results

Eligibility for inclusion in the Compendium has been evaluated by WHO and the external technical advisers listed in the Acknowledgements. However, the evaluation has been solely based on a limited assortment of data including information submitted in applications and when available additional identified public sources. There has been neither physical testing nor rigorous review for safety, efficacy, quality, applicability, or cost acceptability of any of the technologies. Therefore, inclusion in the Compendium does not constitute a warranty of the fitness of any technology for a particular purpose. Besides, the responsibility for the quality, safety, and efficacy of each technology remains with the developer and/ or manufacturer and/or user.

The decision to include a particular technology in the Compendium is subject to change on the basis of new evidence that may subsequently become available to WHO. Inclusion in the Compendium does not constitute an endorsement, or warranty of the fitness, by WHO of any technology for a particular purpose, including in regard to its safety and/or efficacy. Inclusion in the Compendium solely aims to draw stakeholders' attention to innovative health technologies, either existing or under development, with a view to fostering the development and availability of and/or access to new and emerging technologies that are likely to be accessible, appropriate, and affordable for use in low-and middle-income countries.

WHO does not warrant or represent that:

- The list of innovative health technologies is exhaustive or error free.
- The technologies that are included in the Compendium will be listed in future editions of the Compendium.
- The technologies listed have obtained or will obtain regulatory approval for their specified use or any other use in any country of the world, or that their use is or will otherwise be in accordance with the national laws and regulations of any country, including but not limited to patent laws; and/or that
- Any product that may be developed from the listed technologies will be successfully commercialized in target countries, or that WHO will finance or otherwise support the development or commercialization of any such product.

WHO disclaims any and all liability and responsibility whatsoever for any injury, death, loss, damage, use of personal data, or other prejudice of any kind that may arise as a result of, or in connection with, the procurement, distribution, and/or use of any technology embodied in the Compendium, or of any resulting product and any future development thereof. Developers whose technology has been included in the Compendium shall not, in any statement of an advertising, commercial, and/ or promotional nature, refer to their participation and/or inclusion in the Compendium. In no case shall the latter use the WHO name and/or emblem, or any abbreviation thereof, in relation to their business or otherwise.

Executive summary

Appropriate, affordable, effective, safe, high-quality technologies are essential for delivering optimal patient care and improving population well-being. Low-resource settings, however, often have difficulty in identifying technologies that meet their specific needs, resulting in a lack of access to basic health technologies for disease prevention, protection, screening, diagnosis, treatment, rehabilitation and overall management of diseases. Nevertheless, innovative health technologies hold promise for addressing these challenges and potentially provide solutions to unmet needs in underserved communities.

Despite the increasing burden of noncommunicable diseases (NCDs), many health systems are ill-equipped to address this challenge, particularly in low- and middle-income countries (LMIC). NCDs claim 41 million lives annually, representing 74% of global deaths, and 17 million people every year die from NCDs before they reach the age of 70. A significant proportion, 86%, of premature deaths and 77% of all NCD deaths occur in resource-constrained regions. Cardiovascular disease is the leading cause of NCD fatalities, claiming 17.9 million lives annually, followed by cancers (9.3 million), chronic respiratory diseases (4.1 million) and diabetes (2.0 million, including deaths from diabetes-related kidney disease). Collectively, these diseases account for over 80% of premature NCD-related deaths, emphasizing the need for targeted interventions in LMIC *(9,10)*. Therefore, the 2024 Compendium focused on NCDs but also examined submissions for other health priorities.

The Compendium provides a selection of innovative technologies at various stages of development: commercially available, newly commercialized and prototypes. Health technologies are selected for the Compendium in five steps: an open call, initial screening, WHO assessment, deliberation and recommendation by the STAG MEDEV, and WHO validation. In summary, the open call invites submissions, which are screened for completion and relevance. Complete submissions are then assessed by an expert panel for: clinical characteristics, adherence to WHO technical specifications (when available), regulatory compliance, HTA, HTM, intellectual property and feasibility of local production. The results are reviewed by the STAG MEDEV, which subsequently deliberate and recommend the technologies. WHO then conducts a final review to ensure alignment with WHO guidance, and those that do not conform are removed. The aim of this method is to select innovative technologies for addressing health-care challenges in low-resource settings while maintaining WHO standards.

The 2024 Compendium contains WHO assessments of 21 health technologies. They are classified as commercially available (13), newly commercialized (three), prototypes (four) and updates with a full assessment (one). Each technology is described on three pages, accompanied by a synopsis of the product specifications provided by the developers and a synthesis of the assessment, including relevant WHO guidance. The Compendium also includes seven minor updates that didn't need a full assessment.

The Compendium presents promising technologies, encourages more innovation in the field and raises awareness of the pressing need for suitable, affordable solutions for low-resource settings. Its aim is to encourage more interaction among stakeholders, including ministries of health, procurement officers, donors, technology developers, manufacturers, clinicians, biomedical engineers, academics and the public, by providing relevant information and evidence-based assessments of each technology to ensure investment in appropriate health technology and to increase global access to health technologies.

All past editions of the Compendium are available at https://www.who.int/activities/accelerating-impact-for-innovations-for-health.

1. Objectives

The objectives of this Compendium are to:

- select innovative technologies for use in screening, diagnosis, treatment, monitoring and overall management of diseases by evaluating their appropriateness, quality and safety;
- select innovative technologies that could be produced locally or transferred for submission to the health technology access pool (H-TAP);
- provide technical information on prototypes to aid development of suitable design solutions aligned with desirable clinical outcomes;
- support adoption of evidence-based procurement decisions by nongovernmental organizations, governments and other relevant stakeholders; and
- promote awareness and understanding of appropriate technologies among stakeholders, including ministries of health, procurement officers, donors, technology developers, manufacturers, clinicians, biomedical engineers, academics and the public in order to increase investment in high-quality health care by universal access to essential health technologies.

2. Methods

WHO uses a comprehensive method for selecting health technologies for inclusion in the Compendium. The method comprises: an open call, initial screening, WHO assessment by a panel of external experts, deliberation and recommendation by the STAG MEDEV and validation by WHO technical teams for allignment with WHO guidance (Fig. 1).

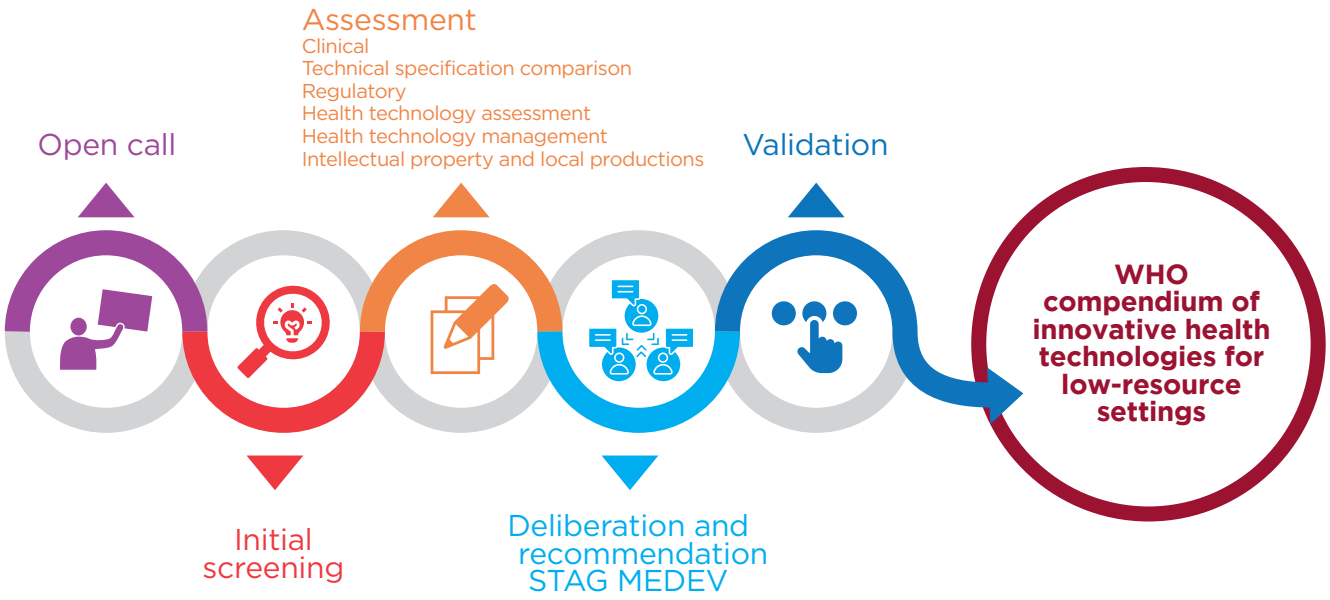


Fig. 1. Overview of the method for selecting technologies for inclusion in the 2024 WHO Compendium of innovative health technologies for low-resource settings

In summary, the open call was an invitation for submissions (October 2023), which were screened for completion and relevance (mid-October to mid-November 2023). Complete submissions were then assessed by a panel of external experts: clinical characteristics, comparison with WHO technical specifications, regulatory compliance , HTA, HTM, intellectual property and feasibility of local production as part of the WHO assessment (November to mid-December 2023). The results were reviewed by the STAG MEDEV, which subsequently deliberated and recommended certain technologies (first two weeks of December 2023 and mid- to the end of January 2024). WHO staff then validated submissions to ensure alignment with WHO guidance (mid-January to mid-March 2024); those submissions that did not conform were removed (Fig. 2). The aim was to select innovative technologies for addressing health-care challenges in low-resource settings while maintaining WHO standards. It is important to note that the assessment process was not linear but iterative. Feedback from the STAG MEDEV and WHO staff was considered in the assessment. Before publication, all the assessments were shared with the innovators. The innovators of the selected technologies were invited to review the results and identify potential errors. All documentation was integrated and prepared for publication during March and April 2024.

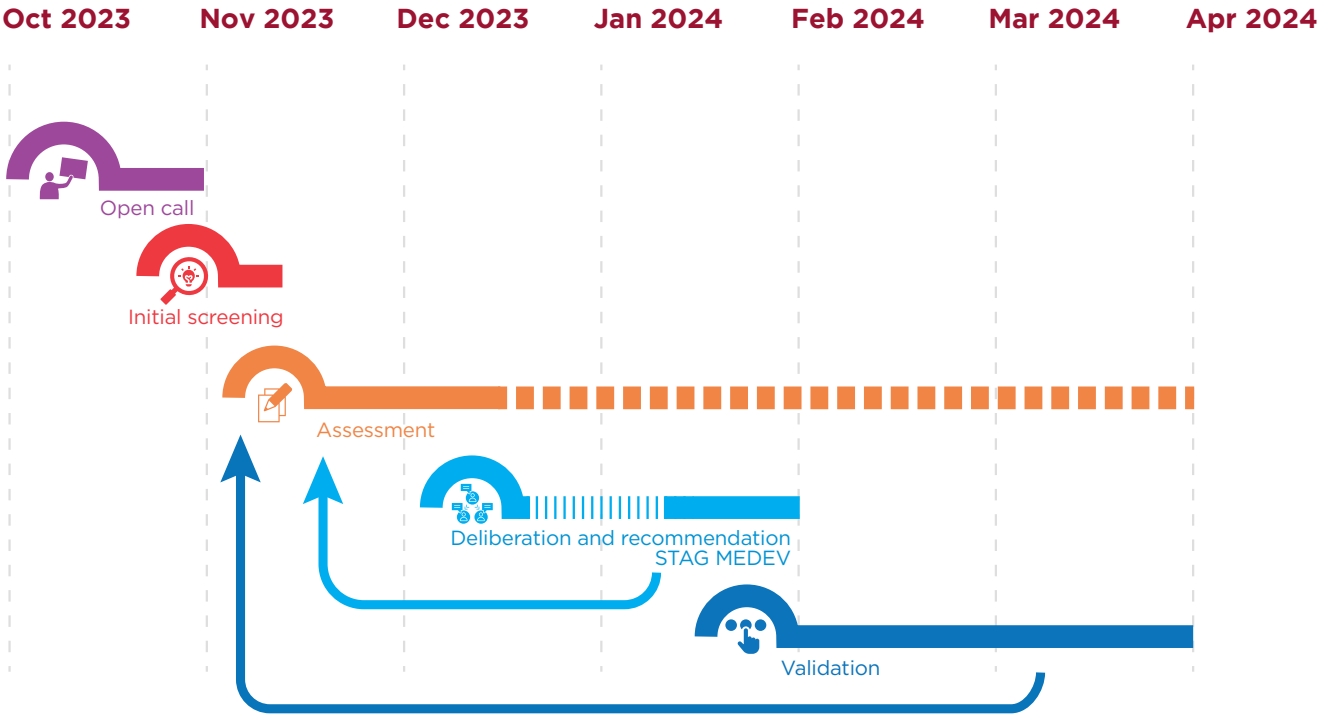


Fig. 2. Timeline and method of selection of technologies for the WHO 2024 Compendium

In 2023, WHO received 225 submissions, comprising 102 commercially available technologies, 94 prototypes and 29 updates. After initial screening, 63 technologies were identified as complete and relevant. One innovator withdrawn its applications at this point. Thus, 62 technologies were assessed by the expert panel. The results were shared with the STAG MEDEV. After deliberation and voting, the STAG MEDEV recommended 30 of the technologies. These were validated by WHO teams with relevant expertise, resulting in 23 new technologies including one update (with a full assessment). After full assessment, two submissions were withdrawn. Seven technologies with minor updates were also included in the 2024 Compendium, for a total of 28 technologies, which comprised 13 commercially available, three newly commercialized, four prototypes, one update with a full reassessment and seven with minor updates (Fig. 3).

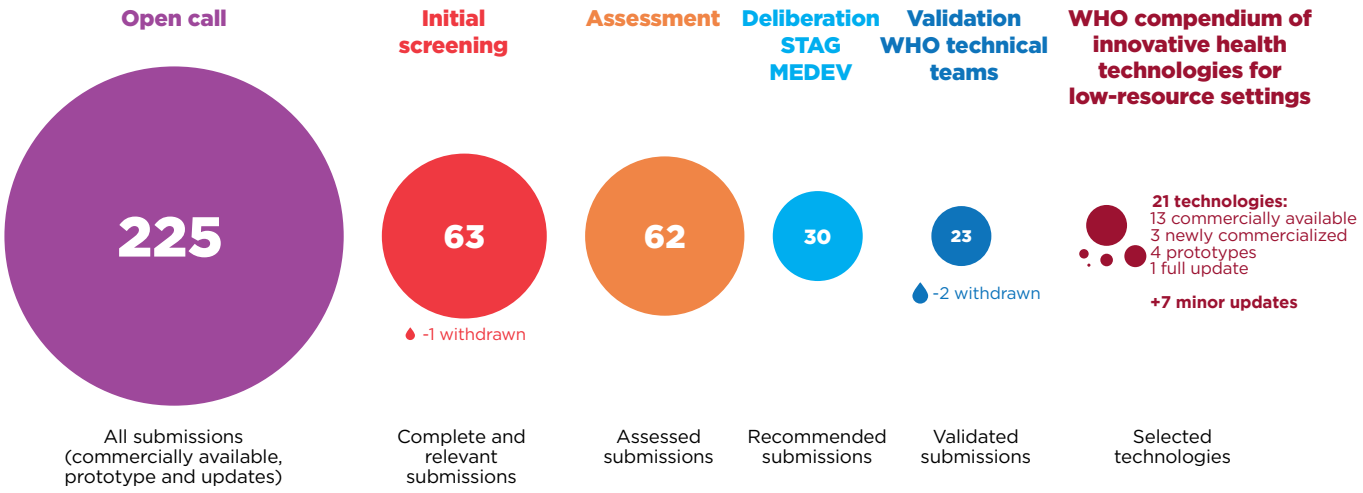


Fig. 3. Numbers of technologies selected at each step of the method

2.1 Open call

An open call was announced on the WHO website and disseminated in the *WHO Medical Devices Monthly Newsletter* between 29 September and 31 October 2023. The call invited submissions of commercially available technologies and prototypes, particularly for NCDs, but submissions of other health priorities were also received. For the first time, the submissions included updates of technologies previously listed in the Compendium. Innovators with technologies in previous Compendia were invited to submit updates or new technologies. All innovators were asked to submit their technologies electronically via a WHO online platform, to complete a questionnaire that included sections for contact details, details of the technology, the clinical conditions addressed by the technology, technical specifications, regulatory assessment, information referring to HTA and HTM, information on intellectual property (IP) rights and the feasibility of local production. The submission form requested innovators to include evidence to substantiate all claims in both published and unpublished documentation. For the subsequent assessment, all evaluators were bound by a confidentiality agreement and a disclosure of interests.

The updates were special cases and were assessed in two steps: a concise submission summarizing the updates, and, if new evidence was provided for consideration, a request for a full submission and a full assessment. A simple update, such as an updated list price, did not require a complete assessment.

2.2 Initial screening

While the call was still open, the submissions were screened to ensure their completeness and relevance. Weekly reminders were sent to encourage completion, and a mid-point screening was conducted to identify incomplete submissions. Even if complete, submissions without the mandatory dossier documents were considered incomplete, and innovators were notified to rectify the omission. Once the call was closed, final screening was conducted for completion and relevance. Incomplete submissions and submissions that were outside the scope of the call were disqualified. Only submissions with a completed questionnaire and a dossier containing all the mandatory documents were considered for assessment.

2.3 Assessment

A multidisciplinary panel of experts was commissioned by WHO to conduct the assessments. Each expert completed a declaration of interests and a confidentiality undertaking. The assessment comprised six areas, with experts assigned to review each section and complete a WHO assessment form. Technologies were assessed in the following areas: clinical, comparison with WHO technical specifications, regulatory, HTA, HTM, IP and local production. Each section included indicators for evaluation (Fig. 4) from the data provided with the submission, including answers to the questionnaire and the attached documentation. The call clearly stated that the evidence was to be assessed. Therefore, the results were derived by reviewing only the evidence provided by October 2023 on the submission form. WHO did not conduct exhaustive investigations of the technologies if evidence was not provided on the submission form. The data collected on the submission form are summarized on Fig 4. Weekly meetings and a dedicated forum facilitated discussion and information-sharing among the expert panel. To ensure consistency, evaluation forms were provided for each area of assessment. Once a form was completed, the score for each indicator and the assessment summary were entered into an online platform, which facilitated management of the assessments for review by the WHO compendium secretariat. It should be noted that the assessments were based on information and evidence provided by the innovators.

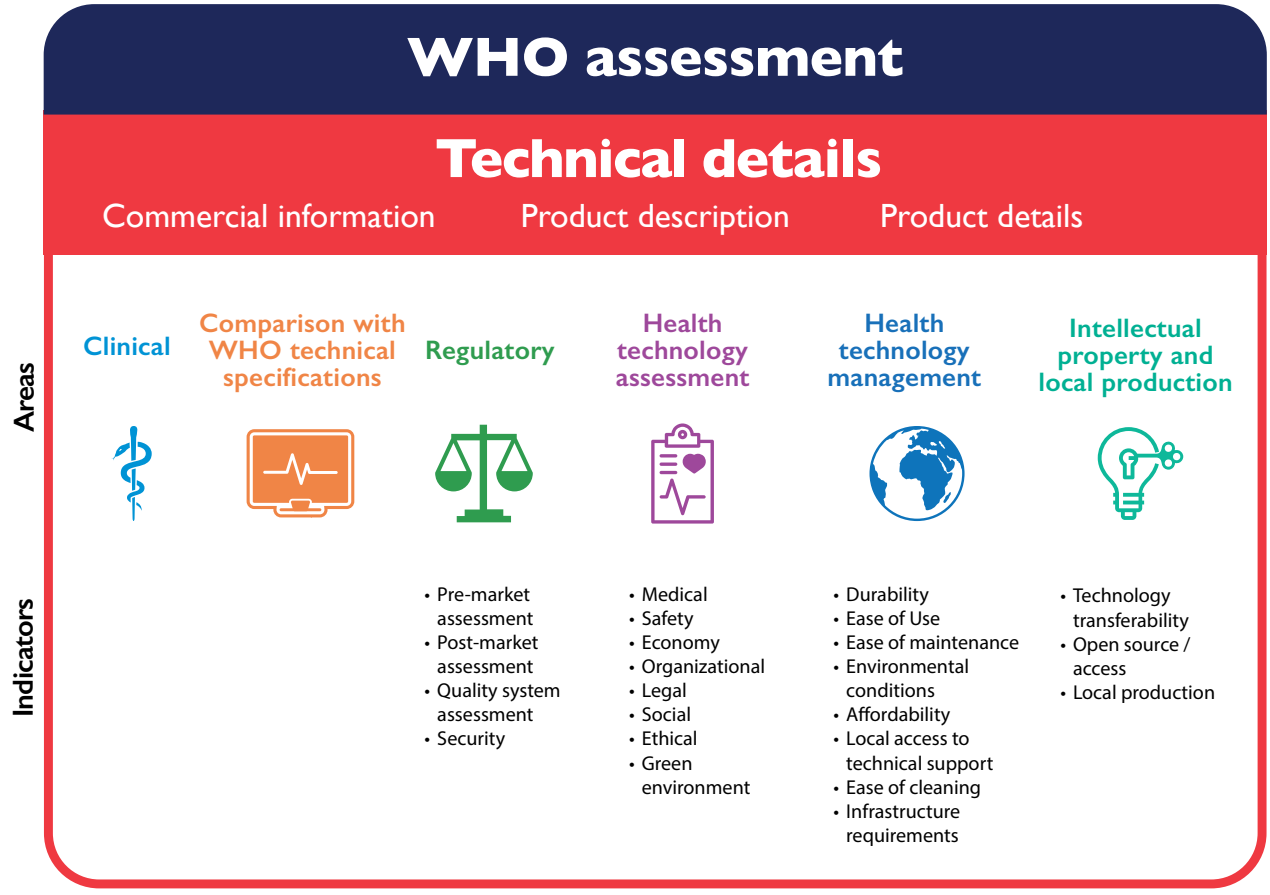


Fig. 4. WHO assessment areas and indicators and data collected for the assessment

Clinical. Each health technology submitted was comprehensively assessed by a clinician previously involved in evaluation of technologies for editions of the Compendium. The assessment covered all the clinical characteristics associated with use of the technology, including the health problem addressed, medical indications and intended clinical use. The assessment was based on information provided by the innovator, and WHO clinical recommendations and related documents were used as primary references. In the absence of WHO guidance, guidelines and recommendations of major scientific

societies were considered. Clinical and epidemiological data were compiled from the latest WHO materials and resources. The assessment results and conclusions for each product were summarized on the WHO assessment form and entered onto the online platform.

Comparison with WHO technical specifications. The proposed technology was compared with technologies listed in WHO lists of Priority Medical Devices and with WHO technical specifications *(11).* All WHO technical specification are available in the WHO Medical Devices Information System (MeDevIS). When available, each technical characteristic in user manuals, clinical guidance, technical manuals and brochures was compared with WHO technical specifications. The findings were summarized on the WHO assessment form and entered onto the online platform, the features of each technology being categorized as either compliant, non-compliant or not verified. The assessment was conducted by a biomedical engineer who had previously evaluated technologies for the Compendium and been involved in developing technical specifications for WHO.

Regulatory. Regulatory evaluation was conducted by an expert regulator with previous involvement in evaluating technologies for the Compendium, who used the WHO regulatory assessment form and an additional template. The WHO form requires documentation and details of the technology to evaluate four indicators: pre-market, post-market, quality system and security. The template, which was developed to align with recommendations of the International Medical Device Regulators Forum (IMDRF) and to include suggestions from WHO technical specifications, accommodates assessments in various regions with diverse content requirements. By combining IMDRF documents, such as the tables of contents for in-vitro and non-in-vitro diagnostic medical device market authorization, the template for regulatory assessment covers establishment details, general information, regulatory requirements, quality management system and security.

The assessment began with a thorough review of the innovator's application and extraction of relevant information for the regulatory assessment template. The WHO form was updated according to the assessment and gap analysis, and final decisions were recorded after evaluation of each indicator. The assessment results and conclusions for each product were summarized and entered onto the online platform.

Health Technology Assessment. The HTA of evidence was performed by the Health Technology Assessment Division of the International Federation of Medical and Biological Engineering in collaboration with the Institute of Biomedical Technology, Athens, Greece, which acted as coordinator. The Health Technology Assessment Division launched a call for experts, and 18 reviewers were co-opted. Instructions and the WHO assessment form were prepared and provided to the reviewers by the Compendium secretariat, who monitored progress and was available to solve problems and provide clarifications. All the technologies were assessed from evidence provided on eight indicators: medical, safety, economy, organizational, legal, social, ethical and green environment. When the information was insufficient to reach a decision, additional investigations were conducted. A shared internal file was created to streamline work and monitor progress in assessment by the reviewers and included information on the technologies and on the reviewers, with a link to the online platform for entering the final assessment and scoring indicators. The Institute of Biomedical Technology managed the HTA and provided assistance for smooth, timely completion of the assessments. Internal meetings were conducted among HTA reviewers when necessary.

Two reviewers were assigned to each technology. The first was responsible for the evaluation, and the second provided an independent assessment. After both reviews were completed and agreed, the first reviewer merged the second reviewer's comments into a final evaluation. The procedure went smoothly, over 95% of cases leading to agreement between the reviewers and improvement of the assessments. When the opinions of the two reviewers were incompatible or when the HTA assessment was incompatible with other areas of the assessment (e.g. HTM), a re-assessment was conducted by a third reviewer assigned as "responsible" for the final decision. Finalized assessments were entered onto the online platform.

Health Technology Management. The WHO assessment form contained eight HTM indicators: durability, ease of use, ease of maintenance, environmental conditions, affordability, local access to technical support, ease of cleaning, and infrastructure requirements. Evaluation of each indicator was based on a structured inquiry into the quality of the evidence and information provided, documentation specific to the indicator and the technology itself. Before the evaluation, a core team was identified of four reviewers with extensive field experience with various equipment categories, brands and specific models. The submissions for approval were distributed among the reviewers according to their familiarity with the innovation's purpose and modality. The evaluation comprised two phases.

The first phase was assessment of the evidence submitted for the technology (e.g. instructions for use or user manuals, user and service videos, international distribution portals). In many cases, the evidence was insufficient to assess all eight HTM indicators; for these innovations, the reviewers sought publicly available information and evaluated the technologies according to their experience of both content and context. For example, the evaluators agreed on an ideal range of operational humidity and temperature and indicated this to the innovators for safe use and also for possible improvements to the product.

The second phase was a review and discussion of each innovation evaluated before transfer to the WHO HTM assessment form. The review comprised internal consultations among the four reviewers to harmonize their evaluations and discuss challenges in the outcomes of evidence evaluation. The reviewers also met with the WHO secretariat to agree on systemic issues, alert other reviewers to potentially unsafe product characteristics and use the combined knowledge of the WHO secretariat and other reviewers. The assessment was then summarized and evaluated for the WHO online platform, with final scoring of the indicators as of low, moderate or high appropriateness for low-resource settings.

The HTM assessment was conducted by 12 biomedical engineers from five continents, who also assessed the appropriateness of medical equipment to ensure transparency and visibility for LMIC.

IP and local production. The method used to assess issues related to IP for innovations submitted to WHO involved identifying any associated IP rights, determining ownership and evaluating accessibility and transferability. To identify IP rights, the information provided by the innovators was reviewed, and then a comprehensive search was conducted to verify the evidence and find any IP rights in other regions by searching open databases. Relevant national IP laws were reviewed to determine the scope of any IP rights identified. If any were identified, a brief description of each IP right and its current legal status was added, and they were categorized into registered or unregistered, granted or pending, open access or proprietary (software) and relevant or irrelevant to the IP assessment. A thorough investigation determined the extent of open access or open source for each technology, including rights retained by IP owners over distributed material. The technologies were then graded accordingly. After identification, the ownership of identified IP rights was determined, including the nature of ownership, and background searches were conducted on applicants to clarify their position regarding IP rights.

Additionally, all agreements that could potentially affect technology transfer were reviewed, such as licensing, manufacture and distribution agreements. To reach a conclusion on transferability, several factors were considered: identification and legal status of IP rights, ownership, potential infringement of third-party rights, existing agreements and the IP owner's willingness to transfer the IP. These measures ensured a comprehensive evaluation of IP rights associated with the submitted innovations.

The method for assessing the feasibility of local production accounts for factors that would influence a business case, including technological aspects, regional policies and global competition. Given the variation in production capability among Member States, the assessment compared regional resources with imports, to acknowledge the diverse capacities of LMIC.

To evaluate the maturity of LMIC for manufacturing specific products, the method includes consideration of the principles of affordability, accessibility and availability to ensure a comprehensive assessment that includes long-term supply of spare parts, regardless of economic sanctions. A uniform, impartial evaluation ensures compliance with these requirements. It is based on the framework of the "5Ms" of production management – men, material, machine, method and money – to analyse the potential for local production *(12,13)*.

The evaluations of IP and of local production were commissioned to a WHO consultant with previous expertise in evaluating technologies for inclusion in the Compendium and in the COVID 19-Technology Access Pool.

2.4 Deliberation and recommendation by the STAG MEDEV

The results of the assessments were shared with the STAG MEDEV on an online platform, where the technologies were reviewed, and inclusion in the Compendium was voted upon. A new category, "newly commercialized", was introduced to better classify young technologies entering the market. Voting thresholds were established according to technology category: 75% consensus for commercially available technologies and 60% consensus for newly commercialized and prototypes. The resulting 30 recommended technologies were sent to relevant WHO teams for validation.

2.5 Validation

This step involved validating technologies for alignment with WHO guidelines, guidance and recommendations. Any concern that arose was discussed with the innovator before a final decision was made. Technologies that were not aligned with WHO guidance were removed.

Only the technologies that were approved in all the steps are included in this publication. Health technologies that were not listed are presented in section 5, including not listed, rejected and withdrawn submissions.

3. Template for technology profiles and indicators

Generic name of type of technology

Country of origin | Country name

Primary function | Assistive, conception control, curative/treatment, diagnostic, disinfection, identification, measurement, monitoring, not medical device (other), palliative, prevention, promotion, protection, rehabilitation, surgery, medical device (other) or/and resuscitation

Category | Medical device (including in vitro diagnostics) or/and any other health technology

Image of technology

Commercial information

List price (USD):
Year of commercialization:
Number of units distributed:
Currently marketed in which countries:
Model:

Product description

A concise technical explanation including the underlying functional mechanisms of the technology is provided.

Product details

Accessories:
Consumables:
Warranty duration:
Lifetime:
Energy requirements:
Facility requirements:

Contact name: | Phone: | Web:

Clinical

Clinical

This section provides a brief summary of the clinical assessment. Information is retrieved from user manuals, clinical guidance materials, technical manuals and brochures of the devices on all clinical characteristics related to use of the device, including the health problem addressed, the medical indications and the intended clinical use of the product.

Comparison with WHO technical specifications

This section presents verification of the compliance and non-compliance of the features and technical characteristics of products. The comparison is conducted with devices and generic names on the WHO List of Priority Medical Devices. Technical characteristics were compared with those outlined in user manuals, clinical guidelines, technical manuals and brochures for the devices.

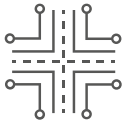
Regulatory

Indicator	Description
Pre-market assessment	Review of all plans, documents and data necessary to support a premarket submission for a medical device or IVD medical device. US FDA and EU MDR/IVDR CE mark requirements are used as benchmarks representative of global regulatory requirements.
Post-market assessment	Review of all plans, documents and data necessary to ensure support of a medical device or IVD medical device after a manufacturer or market authorization holder has received premarket clearance or approval. US FDA and EU MDR/IVDR CE mark requirements are used as benchmarks representative of global regulatory requirements.
Quality system assessment	Review of all plans, documents and data necessary to support a medical device or IVD medical device quality system of a manufacturer and/or market authorization holder. US FDA and EU MDR/IVDR CE mark requirements are used as benchmark representatives for global regulatory requirements.
Security	Review of all documents, data and reports necessary to ensure cybersecurity, digital security and/or biosecurity risks of a medical device or IVD medical device

Health technology assessment

Indicator	Description	Innovation
Medical	Clinical effectiveness of the proposed technology in comparison with the current standard of care or the comparator it is intended to replace	Improvement of health benefit over standard care
Safety	A judgement on the predictability and acceptability of risk (a measure of the probability of an adverse outcome and its severity) associated with use of a technology in a given situation (e.g. for a patient with a particular health problem), by a health professional with certain training or in a specified treatment setting	Improvement of safety profile of the technology over standard care, if any
Economy	Comparison of the costs and consequences of implementing the technology in the targeted settings with those of alternative technologies (e.g. standard of care)	Reduction of the overall costs of managing patients over current standards
Organizational	Evaluation of additional structures, skills, behaviour, compatibility and interoperability with other devices necessary for safe management and delivery of patient care for use of the proposed technology	Improvement of structure, skills and behaviour by use of the proposed technology as compared with standard care, facilitating use
Legal	Extent and degree of transposition of HTA policies into implementing acts (e.g. laws, presidential decrees, administrative acts) for a given national, regional or local societal environment and the extent of compliance among providers, regulators, payers, vendors to the health-care industry and patients, with emphasis on operational, regulatory and transactional issues	Improvement of transposition of HTA policies into implementation of the proposed technology in comparison with any alternatives
Social	Evaluation of perspectives, experiences, attitudes, preferences, values and expectations of patients and users regarding (a) currently used health technologies and (b) the technology being assessed	Improvement of experiences, attitudes, preferences, values and expectations to enhance the intended effect of the proposed technology in comparison with currently used technologies
Ethical	Evaluation of any dilemma that the technology may generate, including its use, the research necessary to generate evidence to support its use and resource allocation	Partial or complete resolution of ethical dilemmas in health systems triggered by the current standard of care
Green environment	Evaluation of the effects of the technology's design materials, production, packaging, transport, distribution, storage, maintenance, destruction and recyclability on the environment, climate change and population health	Reduction of undesirable or unintended environmental effects that use of the technology could generate

Health technology management

Indicator	Description
 **Durability**	Expected ability to withstand environmental and use conditions at the target location
 **Ease of use**	How easily a product can be used safely and effectively
 **Ease of maintenance**	The intensity (frequency, parts replacement and technical skills), and difficulty of technical effort required to sustain the product performance; also applies to software, middleware and hardware (updates and repair)
 **Environmental conditions**	Fulfilment of its intended use under extreme conditions at the site in which it is expected to be used, such as variations in power supply, temperature and humidity and blowing particles and sand
 **Affordability**	The extent to which the intended recipients of a service can pay for it, be it a public, government or private service
 **Local access to technical support**	Availability of technical resources globally to ensure its continuous operation at patient readiness level
 **Ease of cleaning**	Lack of difficulty and/or unique burden of proper cleaning of the product
 **Infrastructure requirements**	Additional functional requirements presented when the product is introduced into the location of use, such as space, utilities, communication, system integration and staff technical competence
 **Locations of use within target settings**	Determination of settings of use for a product from information provided with the submission and survey responses from intended users

Health-care delivery platform

 Community services for primary care	 General outpatient (health post, health centre) and outreach services for primary care
 Pre-hospital emergency services	 First-level (district) hospital services
 Second-level and third-level hospital services and specialized outpatient services	

Intellectual property and local production

Indicator	Description
Technology transferability	Feasibility of and willingness to transfer technical information, tacit know-how, performance skills, technical material or equipment, jointly or as individual elements, with the intent of enabling technological or manufacturing capacity by the recipients
Open source or access	IP that is freely available online or openly sourced to manufacture the product
Local production	Feasibility of producing a technology locally and sustainably in compliance with applicable regulations and technology transfer instructions.

WHO guidance

WHO clinical recommendations, clinical management guidelines and other relevant resources for use of a technology.

Key for icons

Keys for the icons used in the WHO assessments.

WHO assessment					
Clinical	Recommended	Recommended with caution	Not recommended	Not applicable	Not available
Regulatory	Proceed	Proceed with caution	Not acceptable	Not applicable	Not available
Health technology assessment	Recommended	Recommended with caution	Not recommended	Not applicable	Not available
Innovation		Innovation aspect in the following domains: medical, safety, economic, organizational, legal, social, ethical, green environment			
Technology readiness level (TRL)	8-9	5-7	1-4		
Technology evidence assessment	Recommended	Recommend with caution	Not recommended	Not applicable	Not available
Health technology management	High appropriate-ness for low-resource settings	Moderate appropriate-ness for low-resource settings	Low appropriate-ness for low-resource setting	Not applicable	Not available

Intellectual property

Technology transferability	Fully transferable	Proceed with caution	Not transferable	Not applicable	Not available
Local production	High appropri-ateness for low-resource settings	Moderate ap-propriateness for low-re-source settings	Low appro-priateness for low-resource setting	Not applicable	Not available

						
Open source intellectual property	Fully open source	Limited open source	No open source	Not applicable	Open access	Not open access

4. Technology profiles

Commercially available technologies

Commercially available

Aspergillus ICT IgG-IgM*

Country of origin | France
Primary use | Diagnosis/measurement/monitoring
Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 8.73

Year of commercialization: 2018

Number of units distributed: 21380 tests

Currently marketed in: Algeria, Belgium, Burkina Faso, Cameroon, China, Côte d'Ivoire, Democratic Republic of the Congo, France, Gambia, Germany, Ghana, India, Indonesia, Italy, Kenya, Kuwait, Malawi, Morocco, Nigeria, Portugal, Senegal, Sierra Leone, Spain, Togo, Trinidad and Tobago, Uganda, Ukraine, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania

Model: ASPERGILLUS ICT IgG-IgM

Product description

ASPERGILLUS ICT IgG-IgM is a unitary qualitative rapid test based on immune chromatography technology (lateral flow), allowing the simultaneous detection of both IgG and IgM class anti-Aspergillus antibodies in human sera. Each kit is composed of the cassettes and the eluent solution that allows the chromatography. The migration is completed in 20-30 min. The device meets the ASSURED criteria: affordable, sensitive, specific, user-friendly, rapid/robust, equipment-free, and deliverable to users.

Product details

Accessories: Ready-to-use cassettes (in packets of 10, two pack sizes: 20 and 100 tests); Dropper bottle of elution buffer; Instructions for use

Consumables: Micropipette with disposable tips; gloves

Warranty duration: Not applicable

Lifetime: 18 months if kept at 2–8 °C 2 months if kept at room temperature after bag opening

Energy requirements: No

Facility requirements: A refrigerator (2–8 °C) for storing the kits and serum/plasma samples; A centrifuge to obtain serum samples from blood samples and/or heparin/citrate or EDTA tubes to obtain plasma samples

Contact: Denis Limonne | Phone: +33 47 883 3487 | Web: https://rb.gy/spxp3j

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

Chronic forms of aspergillosis are a significant cause of respiratory disease, with important morbidity and mortality. Current diagnostic consensus requires microbiological and histopathological testing, which is not readily available in low-resource settings. Concurrently, populations in these regions are at a disproportionately higher risk of contracting fungal infections such as aspergillosis due to environmental and occupational factors. Timely diagnosis and treatment can substantially relieve the disease burden.

This technology is a unitary qualitative rapid test based on immune chromatography technology (lateral flow) for simultaneous detection of IgG and IgM class anti-Aspergillus antibodies in human sera, used to diagnose chronic forms of aspergillosis, such as chronic pulmonary aspergillosis and allergic bronchopulmonary aspergillosis. It couples low cost with high performance in a well-known format, allowing for rapid deployment in most settings.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer details the technical specifications in the submission form, providing the user manual that correctly supports the declared technical information. Neither UNICEF nor WHO technical specifications available related to ASPERGILLUS rapid tests for immunochromatography (ICT) technology to detect both IgG and IgM classes of anti-aspergillus antibodies. Consequently, at the time of report creation, WHO/UNICEF technical specifications were not available to compare this type of technology.

Regulatory

Pre-market assessment	Proceed
Post-market assessment	Proceed with caution
Quality system assessment	Proceed
Security	Proceed

Pre-market: This product is a Class IIb medical device and has obtained European Union (EU) market approval. The CE certificate is valid until 26 May 2025. The manufacturer submitted partial documentation for the design verification and validation of the product. Consequently, full premarket assessments could not be conducted to ensure the safety and performance of the product.

Post-market: The manufacturer submitted partial post-market surveillance and vigilance documentation. According to the submission, there have been no recalls or adverse events since the release of the product. Nevertheless, it is considered good regulatory practice to establish the PM system before introducing the product to the market.

The CE certificate was submitted. The other regulatory approvals were declared but not submitted; as such they could not be verified.

Quality management system (QMS): The manufacturer has submitted a valid ISO13485:2016 until July 20, 2024 manufacturing certificate. Based on the certification and standards, the manufacturing of the product conforms to ISO13485:2016.

Security: This product does not impose any biosecurity or cybersecurity issues.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	→	💡
Safety	→	
Economy	!	💡
Organizational	!	💡
Legal	!	
Social	!	
Ethical	→	
Green environment	⛔	

As the manufacturer states, this product helps to diagnose aspergillosis in the LMIC context. The kits show adequate sensitivity and specificity, similar to the standard of care and therefore could be used for diagnosis. The aspergillus ICT IgG-IgM is small and transportable, making it suitable for field screening. They claim the results of the test will be ready within 30 min. The documentation presented by the innovator, that use of this device does not present greater risks than than standard care.

The innovator only submitted a price list. The economic impact should depend on the country's economic context. It is important to consider that this kit would be a part of diagnosis algorithm. Use of the kit would have no relevant impact on the organization. The device has ISO14971:2019 and ISO13485:2016 approval and certification from the Agence nationale de sécurité du médicament et des produits de santé in France (country of origin). Use of the device would have no relevant social or ethical impact. It is single-use and cannot be recycled.

Technology readiness level 9

Technology evidence assessment Recommend with caution

Health technology management

Durability	!
Ease of Use	→
Ease of maintenance	N/A
Environmental conditions	→
Affordability	→
Local access to technical support	!
Ease of cleaning	N/A
Infrastructure requirements	!

Health-care delivery platform

The product consists of a kit containing cassettes and an eluent solution. Due to its minimal infrastructure requirements, the test is suitable for facilities with low resources that have only basic equipment and infrastructure. The test is simple to use and involves short training for the user to become proficient, which reduces the need for highly skilled staff.

The unsealed kit should ideally be refrigerated, but it has been demonstrated to be stable at room temperature for up to two months at temperatures up to 30°C. In the field, the kit has been used at temperatures as high as 37°C and humidity levels as high as 90%, suggesting that it is resilient to extreme environmental conditions. Since it is a single-use cassette, no maintenance is required. The disadvantage is the potential environmental impact of the waste from each discarded cassette.

Intellectual property and local production

Technology transferability	!
Open source/ access	🔒
Local production	!

Intellectual property: Protected by trade secret. Clearance to use this technology is required.

Local production: The technology has a compliant manufacturing process. End-to-end manufacture requires a high level of multidisciplinary expertise and specialized infrastructure. Per unit cost can be reduced moderately through local production, but the business case is weak. Hence, the test kit assembly approach in low batch volumes using the least automated process is proposed for LMICs during the initial days.

WHO guidance

- The selection and use of essential in vitro diagnostics. (2022). https://iris.who.int/bitstream/handle/10665/373322/9789240081093-eng.pdf?sequence=1
- WHO fungal priority pathogens list to guide research, development and public health action. (2022). https://iris.who.int/bitstream/handle/10665/363682/9789240060241-eng.pdf?sequence=1

Commercially available

Asymmetric nasal high-flow therapy*

Country of origin | New Zealand
Primary use | Other
Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): N/A
Year of commercialization: 2021
Number of units distributed: >10 000
Currently marketed in: 100+ countries including Kenya, Mali, Malawi, Rwanda, Uganda, and Zambia.
Model: OPT96X

Product description

Optiflow+ Duet is an improvement on the standard nasal high-flow (also called high-flow nasal cannula or HFNC). It has a unique, innovative asymmetric design, the right prong of the interface being larger than the left. The asymmetric nature of the prongs results in a significant improvement in the two primary mechanisms over the standard nasal high-flow therapy. They increase dynamic positive airway pressure and dead space clearance. This results in decreased breathing work for the patient and decreased minute ventilation. It has the added of making it harder to inadvertently occlude both nares and quieter therapy delivery.

Product details

Accessories: Not applicable
Consumables: Not applicable
Warranty duration: Optiflow+ Duet cannula have a shelf life of 3 years. As the product is a consumable it does not have a warranty duration.
Lifetime: 14 days duration of use (single patient use), 3 years shelf life
Energy requirements: Not applicable to Optiflow+ Duet. The flow driver will require energy.
Facility requirements: Not applicable

Contact: Beth Hardy | Phone: +44 7842427824 | Web: https://rb.gy/5oelgg

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

Acute respiratory failure can complicate several acute or chronic respiratory and cardiovascular conditions. A high-flow nasal cannula (HFNC) has become an increasingly popular option to provide supplemental oxygen and respiratory support to spontaneously breathing patients. Advantages include patient comfort, delivery of a warmed and humidified air/oxygen mix, reduced respiratory work through a variable level of positive end-expiratory pressure, and increased dead space washout.

This technology optimizes the nasal cannula with an asymmetrical design, in which the right nasal prong has a larger diameter than the left nasal prong. The effect of this design change is to improve clearance of expired gas from the upper airways by reverse flow via the choanae at the end of expiration, decrease exhalation effort, and reduce noise levels during treatment. Clinical data show that this improves minute ventilation and reduces the work of breathing, with negligible effects on other parameters such as positive end-expiratory pressure. In summary, an asymmetric nasal cannula seems to increase HFNC efficacy and comfort when this modality of respiratory support is indicated.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Based on the technical specifications declared in the submission form and the documentation provided in support, compliance with WHO technical specifications available for the device "Cannula, nasal" (original name of the specifications is "Nasal oxygen cannula with prongs") is confirmed.

With regards to the other, similar WHO technical specification available named "High-flow nasal cannula (HFNC)" unit, as the innovative technology proposed does not include the whole unit (with monitor, displayed parameters, power supply requirements, etc.) but only the patient interface, compliance could be confirmed only for the sections related to consumables and to other technical requirements , such as the adult/paediatric interface of the entire HFNC system.

Regulatory

Pre-market assessment	Proceed
Post-market assessment	Proceed with caution
Quality system assessment	Proceed
Security	Proceed with caution

Pre-market: This product is a Class IIa medical device in the EU and has obtained market approval in Australia, Canada and the EU. The manufacturer claims that design verification and validation test reports have been conducted, but only some of the reports were available.

Post-market: The manufacturer did not submit the post-market surveillance and vigilance documentation. The field safety corrective action plan and recall procedure documentation were not submitted. The regulatory approvals, including market authorizations, were not supported with documents.

Quality management system (QMS): The manufacturer has submitted an ISO13485:2016 certificate valid until 13 November 2024. Based on the certification and standards for performance, the product is safe and effective.

Security: Introduction of this technology does not lead to biosecurity or cybersecurity risks. The manufacturer did not submit complete risk management documentation, risk analysis, risk management plan, risk control, post-production information, and other hazard reports. risk management activities were could not be verified.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical		
Safety		
Economy		
Organizational		
Legal		
Social		
Ethical		
Green environment		

The device is commercially available in over 100 countries, including LMICs, with more than 10 000 units distributed. The innovation proposes a novel way to provide nasal high-flow therapy with an asymmetric design, with the right prong being larger than the left. Studies indicate that it enhances enhanced clinical outcomes and patient safety as compared with the standard of care. The device is CE-marked, and a risk assessment has been performed. The available data are insufficient to prove that the device is cost-effective for LMIC, as exact pricing is not provided. Despite that, the manufacturer claims its price is similar to the standard of care. Because of this similarity, the product can be expected to be easily adopted. Additional equipment, such as a high-flow device manufactured by the innovator or any other high-flow system used with a humidifier produced by the innovator, is needed to guarantee the device's expected functioning, according to the innovator's response. This should be taken into consideration as an additional economic constraint. Other set-ups may be used, but the results are not verified. The innovator provides training and education free of charge.

Technology readiness level 9

Technology evidence assessment Recommend with caution

Health technology management

- Durability
- Ease of Use
- Ease of maintenance — N/A
- Environmental conditions — N/A
- Affordability
- Local access to technical support
- Ease of cleaning — N/A
- Infrastructure requirements

Health-care delivery platform

Optiflow Duet offers an innovation over standard nasal high-flow therapy; it can be used with an Airvo device or a high-flow ventilator, which makes it versatile. It is suitable for low-resource settings because it reduces the possibility of patient escalation, avoiding the need to transfer patients to a referral hospital that may be several hours away. No price information is available. It is important to note that sterile water is required (sometimes difficult to source in the volumes required). This disposable product does not require engineering resources or product maintenance.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: It is protected by trade secrets, patents, registered industrial designs, and trademarks. The use of all intellectual property will require clearance.

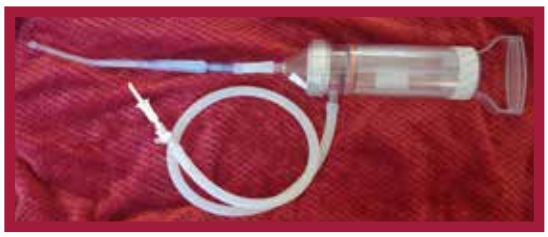
Local production: Current regional volumes are considerably low, weakening the business case for dedicated local production. However, this can be a promising product if volumes increase in the years to come.

WHO guidance

- Clinical management of COVID-19: living guideline. (2023). https://iris.who.int/bitstream/handle/10665/372288/WHO-2019-nCoV-clinical-2023.2-eng.pdf?sequence=1

Commercially available

Autologous blood transfusion device*



Country of origin | United States of America

Primary use | Treatment/resuscitation/palliative care/surgery

Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 2750

Year of commercialization: 2019

Number of units distributed: 2900

Currently marketed in: Ghana, Kenya, South Africa and United Republic of Tanzania

Model: 9100

Product description

Sisu designed Hemafuse to enable clinicians to use a patient's own blood to save them in cases of internal bleeding. This simple, handheld mechanical surgical device can salvage blood from a surgical site, filter that blood, and re-transfuse blood back to that same patient during trauma or planned surgery when the blood is pooled internally.

Product details

Accessories: Inlet port accessories consists of a suction connector and a Yankauer tip. These two allow the user to easily manoeuver and suction blood. They connect to the short tubing suction and allow blood to flow into the Hemafuse™ pump. A short tubing section connects from the inlet port of the device and allows blood to flow into the device. A long tubing section connects from the outlet port of the device and allows blood to flow to the blood bag. Outlet port accessories consist of a stopcock connector, stopcock, and blood bag spike with spike cap. These are connected to the long tubing section to provide an adapter to fit into the blood bag as well as allow for air release from the device before operation.

Consumables: The Hemafuse filter and accessory kit are single-use disposable and therefore must be changed for each patient. Additional consumables required are a single blood bag that is pre-filled with citrate and a standard patient infusion set.

Warranty duration: Shelf life of the Hemafuse filter and accessory kit is approx. 3 years. Hemafuse pump is reusable after cleaning and sterilization up to 25 times

Lifetime: 3 year shelf life for filter and accessory kit and 25 sterilization cycles for the pump.

Energy requirements: Manual operation. Requires an autoclave for sterilization.

Facility requirements: The Hemafuse™ system components must be stored below 30°C.

Contact: Gillian Henker | Phone: +1 41 272 19269 | Web: https://rb.gy/jiwtdr

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

Worldwide, there is a shortage of blood donations, which affects access to blood products. In low-resource settings, this shortage is compounded by the lack of adequate facilities and qualified health-care practitioners. Autologous transfusions, which do not require complex compatibility testing, are commonly conducted by surgeons and anaesthesiologists to resuscitate patients in haemorrhagic shock. However, due to the lack of specialized equipment, resourceful yet potentially dangerous solutions are used.

This technology provides an easy-to-use, safe alternative to these practices, which allows surgical staff to quickly assemble and deploy the device and reuse the patient's own blood. It can also supplement allogeneic donor blood components. Autologous transfusion safety is ensured by the use of specific filters, single-use sterile circuits, and sterilizable hand pumps. This allows for judicious use of the scarce blood components and is a last resort technique when no allogeneic blood components are available.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

Instructions for use have been provided, but they are missing many characteristics of a complete user manual and they do not include technical specifications. At the time of report creation, WHO/UNICEF technical specifications were not available to compare this type of technology.

Regulatory

Pre-market: This product is a Class II medical device in the USA and has been approved as a single-use device in this market. Additionally, the product has obtained regulatory approvals in Ghana, India, Kenya and the United Republic of Tanzania.

The manufacturer submitted partial documentation for design verification and validation of the product. Consequently, full premarket assessments could not be conducted to ensure the safety and performance of the product.

Post-market: The manufacturer submitted partial post-market surveillance and vigilance documentation. According to the submission, there have been no recalls or adverse events since release of the product. Nevertheless, it is considered good regulatory practice to establish the post-marketing (PM) system before introducing the product to the market.

Quality management system (QMS): The manufacturer submitted a valid ISO13485:2016. An establishment license and product registration were submitted. These certifications and standards for performance assure that the product is safe and effective.

Security: There is no evidence of biosecurity or cybersecurity risk for this product. The manufacturer submitted risk management documentation.

Health technology assessment

In low-resource settings (LRS), where the standard of care (SoC) is a scoop and strain method, the innovation can reduce infections and clotting diseases. No adverse events have been reported through its use cases (over 200 in four LMICs) with 2900 distributed units. A risk assessment plan has been performed according to ISO 14971, and a couple of case studies and reports showcase its medical effectiveness. However, more peer-reviewed evidence would be needed to make a more confident recommendation. Compared to other autotransfusion systems, this innovation is manually operated, meaning no electronic waste is produced, and it can be easily implemented in LRS. The device is reusable up to 25 times, though its use could be expanded to further reduce plastic waste. Its use case is straightforward and can be utilized easily by skilled surgical teams with little training time. The cost-effectiveness of the innovation is relevant to the cost of blood units in different countries and is under examination by the innovator.

Technology readiness level 9

Technology evidence assessment Recommend with caution

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The Hemafuse is a mechanical (hand) pump to recover, collect, and give back blood from and to patients during operations. It is easy to use and easy to clean, and the main part is autoclavable and reusable. The documentation provided is complete and readable, and shelf durability testing has been done.

There are some concerns: The device is said to function up to 30°C. In some LMIC settings, operating theatres might reach higher temperatures. The same counts for shelf life testing at 23°C. No spare parts are available, while potentially parts of the Hemafuse could be replaced. However, the device has a lifetime of 25 uses only, with single-use consumables for each patient. Having a longer lifetime would be interesting and maybe justify the price. The price seems steep compared to the production cost, and the cost per operation is not negligible.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: It is patent-protected with registered trademarks. The use of all intellectual property will require clearance.

Local production: The product has a compliant manufacturing process. However, the key manufacturing know-how is likely to be with the contract or licensed manufacturers. The per unit cost can be reduced moderately with local production; however, it should be noted that the product is currently in the verification and validation phase. This product has a moderate business case, as the market positioning of this product in the region can be critical and can affect manufacturing volumes. The tooling required for some of the key components is expected to be complex.

WHO guidance

- Educational Module on Clinical Use of Blood (2022)
  https://apps.who.int/iris/bitstream/handle/10665/350246/9789240033733-eng.pdf

Commercially available

Clinical laboratory analyser/instrument control unit IVD*

Country of origin | China

Primary use | Diagnosis/measurement/monitoring

Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 2500

Year of commercialization: 2022

Number of units distributed: 250

Currently marketed in: Brazil, Germany, United Kingdom of Great Britain and Northern Ireland, India, Norway and United States of America

Model: iaX-2101 rapid diagnostic reader

Product description

The iaX universal rapid diagnostic reader (RDR) can quickly and accurately read antigen, antibody, and biomarker rapid diagnostic tests (RDT) based on lateral flow technology in seconds, providing critical data for medical professionals and patients alike. It has camera-based supporting colourimetry and fluorescence assays with integrated ambient, UV, and IR light sources. It supports multiplex test strips or self-test cassettes and Assaya LEIQA data matrix reading. It is approved for US FDA Class 1 IVD 510K.

Product details

Accessories: Mains power supply; Rechargeable battery; Bar code scanner; USB cable; Travel case.

Consumables: The iaX supports any brand or type of rapid diagnostic test (RDT).

Warranty duration: 3 years

Lifetime: 10 years / 10 million reads

Energy requirements: Battery or mains powered.

Facility requirements: No specialized requirements; it can be used in a field setting in a LMIC or a laboratory.

Contact: Abri-Elle Sivertsen | Phone: +1 678-234-1775 | Web: https://rb.gy/o6jaw0

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

Rapid diagnostic tests (RDT) are increasingly important, as they provide quick and reliable results for different conditions with very few additional resources. Test interpretation can be difficult, and there is a risk of misinterpretation due to human error. This product is a small-dimension instrument that reads several types of RDTs (antigen, antibody, and biomarker tests based on lateral flow technology) from different manufacturers (cassettes and cards). It gives a reading in seconds and can store the results in a database. RDT readers promote more consistent, accurate test performance, interpretation, and reporting, replacing the human operator in the interpretation of test results.

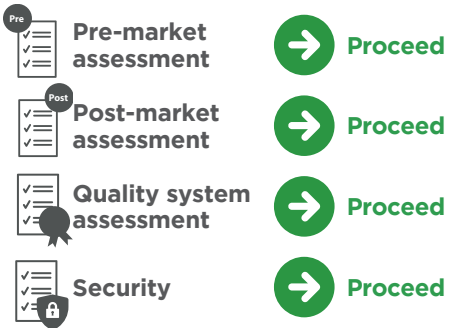
** This assessment was initiated November 2023

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer provides specifications for all needed technical features and related supporting documents. At the time of this report's creation, WHO technical specifications were not available to compare this type of technology.

Regulatory



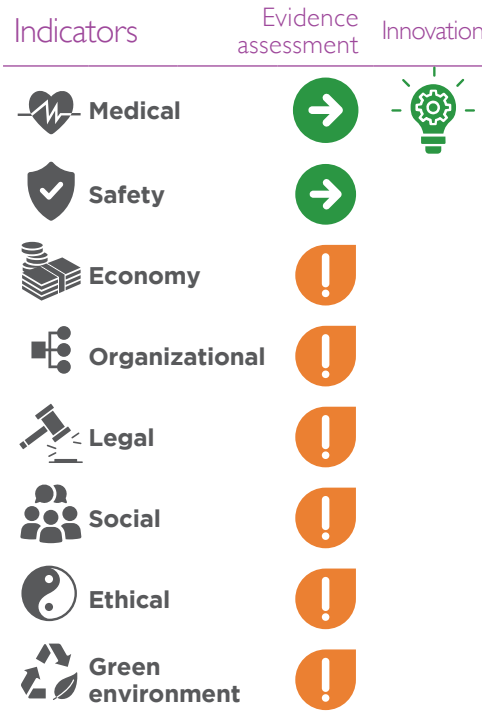
Pre-market: This product is a Class I medical device. The product has obtained market approval in the EU. Based on the certification and standards for performance, the documentation submitted is adequate to demonstrate that the product is safe and effective.

Post-market: The manufacturer has submitted post-market surveillance and vigilance documentation to monitor the safety and effectiveness of the product after placement in the market.

Quality management system (QMS): The manufacturer has submitted a valid ISO13485:2016. Based on the certification and standards, the manufacturing of the product conforms to ISO13485:2016, and the product is safe and effective.

Security: The manufacturer has submitted a risk management report, risk analysis, risk evaluation, risk control, and risk analysis documentation. Consequently, risk and control measures are in place to monitor the effectiveness of the controls. The manufacturer has declared conformance to IEC62304 software validation for the lifecycle of the device, demonstrating that this technology does not lead to cybersecurity risk. The manufacturer has conducted the EMC test to ensure the basic safety and essential performance of the product for electromagnetic disturbances and electromagnetic emissions of ME equipment and ME systems.

Health technology assessment



The Assaya iaX offers rapid and accurate diagnostic readings in clinical and non-clinical settings. Safety testing aligns with regulatory standards, reporting acceptable results without adverse clinical effects. Economically, the device shows promise due to its universal compatibility, potentially halving costs compared to traditional test-specific reactions. While limited evidence hinders a comprehensive organizational evaluation, indications suggest minimal organizational changes or workforce additions due to the device's compatibility with various tests. Insufficient evidence is provided for legal, social, ethical, and environmental evaluations, but preliminary data indicates cultural acceptance and potential sustainability advantages. The device showcases innovation through its universal compatibility and optimized technology with reduced human error, making it a significant advancement in diagnostics.

Technology readiness level 9

Technology evidence assessment Recommend with caution

Health technology management

Durability
Ease of Use
Ease of maintenance
Environmental conditions
Affordability
Local access to technical support
Ease of cleaning
Infrastructure requirements

Health-care delivery platform

The iaX-2101 is a portable computer vision system that uses a camera, multi-colour LEDs, and integrated computing to read and analyze lateral flow assays. It has several features that make it ideal for low-resource settings. Any health worker with minimal training can operate it, and it requires minimal infrastructure. It can read the tests from a variety of manufacturers, meaning that organizations can avoid purchasing multiple different readers that are compatible with the lateral flow assays from various vendors. It is suitable for field use or in locations with limited access to electricity because it can run on a power outlet or a rechargeable battery.

Although user maintenance is simple, the manufacturer is responsible for all corrective maintenance. This may present a challenge in the absence of a local presence in the countries. Given the device's sensitivity to being dropped, a more durable construction might be advantageous for use in the field.

Intellectual property and local production

Technology transferability
Open source/ access
Local production

Intellectual property: The technology is protected by patents, trade secrets, copyright, utility models, and trademarks. The status of some of the patent applications is pending. The use of all intellectual property will require clearance. Caution is advised due to the pending patent application.

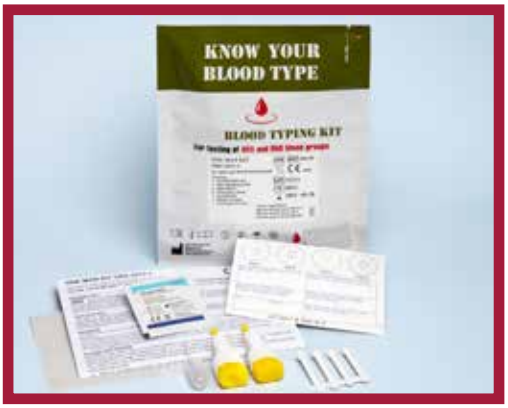
Local production: Based on available evidence, the product and manufacturing process are compliant with applicable regulatory norms. However, the manufacturing know-how of this device is likely to be with the contract manufacturer, and components will be mostly import-dependent for LMICs. Though the technology and manufacturing know-how are already in an optimal cost environment, local production may enable the company to achieve further moderate cost reductions in response to the likely increase in demand for this technology. This is a good technology that can be considered for local production.

WHO guidance

- Target product profile for readers of rapid diagnostic tests. (2023). https://iris.who.int/handle/10665/365980
- "Strengthening diagnostics capacity" seventy-sixth World Health Assembly, Agenda item 13.1, WHA76.5, (30 May 2023) https://apps.who.int/gb/ebwha/pdf_files/WHA76/A76_R5-en.pdf

Commercially available

Dry format card for ABO blood groups and Rhesus factor typing point-of-care test*



Country of origin | Denmark

Primary use | Diagnosis/measurement/monitoring

Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 1.5

Year of commercialization: 2002

Number of units distributed: 22 000 000

Currently marketed in: Germany, Denmark, Finland, United Kingdom of Great Britain and Northern Ireland, Indonesia, Israel, Mexico, Mali, Mozambique, Netherlands, Norway, United States of America, Viet Nam, South Africa and Zimbabwe

Model: EldonCard 2511 and EldonCard 2521

Product description

The EldonCard is a dry-format card for ABO blood groups and Rhesus factor typing point-of-care tests. It can be used for point-of-care everywhere. The EldonCard is extremely accurate. It has been tested against the standard blood typing procedure using direct agglutinating antibodies. Tests have been performed at several laboratories in different countries, and the result is that there is a 99.9% concordance between the results achieved by the EldonCard and a test using a well-executed standard blood typing procedure.

Product details

Accessories: The EldonCard is normally delivered with EldonSticks, alcohol swaps, auto lancets, pipette (for transferring 4 drops pf water on to the card), an EldonFoild to put over the dried EldonCard, and full instructions for use. The EldonStiks cannot be sourced from other suppliers as it is unique to the use of the EldonCard.

Consumables: The EldonCard requires 4 drops of potable water to complete one test.

Warranty duration: The EldonCard can be stored at room temperature (5-37°C) and has a shelf-life (warranty duration) of 24 months after production at said conditions.

Lifetime: 24 months from production.

Energy requirements: None

Facility requirements: The EldonCard can be used point-of-care everywhere. It can be used in: The blood bank, the clinic (also very basic clinics), the hospital, the laboratory, a private home.

Contact: Peter Lunding | Phone: +45 2222 9238 | Web: https://rb.gy/7f6zsk

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

This technology intends to reduce the burden of Rh haemolytic disease of the fetus and newborn and complications and expand access to blood typing in settings with limited access to laboratory services. For women living in low-resource countries, access to blood type testing during their pregnancies may be limited. With this technology, blood typing is fast (results in two minutes) and accurate. This can accelerate the access to prophylactic treatment to avoid Rhesus disease and complications, as well as facilitate blood transfusions.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer provided the necessary detailed technical specifications, also supporting their declarations with technical documentation (that is, instructions and user manual). At the time of this report creation, WHO technical specifications were not available to compare this type of technology.

Regulatory

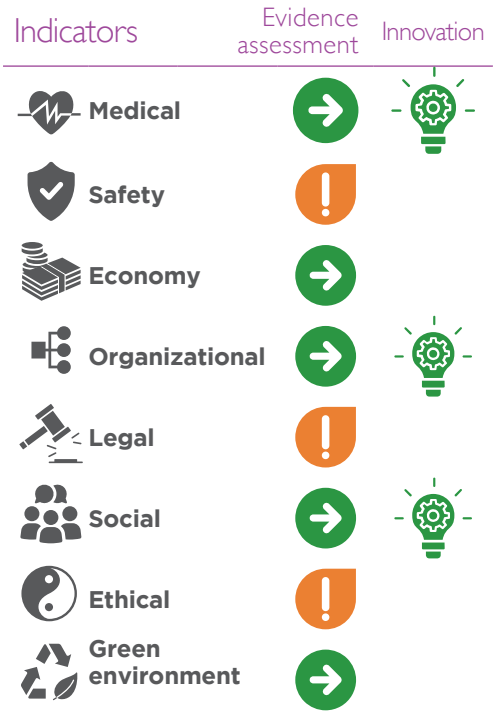
Pre-market: The product has obtained market approval in the USFDA, EU, Bangladesh, Ghana, Indonesia, Kenya, South Africa, Vietnam and Zimbabwe. However, adequate documentation was not provided to perform a regulatory review on the performance of this product.

Post-market: The manufacturer declared that they have some of the post-market documentation but did not submit the post-market surveillance and vigilance documentation. According to the submission, there have been no recalls or adverse events reported. Nevertheless, it is considered good regulatory practice to establish the complete PM system before introducing the product to the market.

Quality management system (QMS): The medical device manufacturing is certified to ISO13485:2016 standard and demonstrates that the device is safe and performance is in accordance with the intended use.

Security: The manufacturer did not submit risk management systems documentation essential to ensure the safety and performance of the device.

Health technology assessment



Since its commercialization in 2002, 22 million units of this product have been distributed in the EU, USA and various LMICs. This is a CE marked and FDA cleared product. Studies suggest that it provides substantial medical benefits, particularly in LRS, overcoming challenges associated with traditional blood typing methods. Its portability, immediate result deliverance, and durability without the need for cold chain and storage make it practical and efficient. The product shows great concordance compared with standard blood typing procedures. However, one should be aware that it does not provide for sub-groups (A1, A2, A1B & A2B). Although safety concerns are expected to be minimal, a detailed risk analysis is missing. Economically, the product costs approximately 1.50 USD per test. Compared to standard blood typing techniques that are susceptible to power loss induced waste, consumables end-of-life and cold storage requirements, this product can be cost effective. Organizational integration appears seamless, requiring no significant changes, workforce adjustments and facility requirements. The test result card can be added in the patient's medical file. Overall, this product can offer a solution to blood typing, as well as Rhesus disease prevention in LMICs. The overall CO2 foot print of the device is by its nature low, and the innovator seems sensitive to enviromental issues, by using green electicity.

Technology readiness level 9

Technology evidence assessment Recommended

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The EldonCard is a dry blood typing test demonstrating 99.9% concordance with standard blood typing procedures, making it a reliable diagnostic tool. Paper cards are individually packed in envelopes of durable aluminium or plastic foil to preserve them during shipping or storage. The cards have a 24-month shelf-life at room temperature (5 to 37°C), suitable for diverse storage conditions. The EldonCard manual has clear visual instructions that provide use and testing guidance and examples of possible blood reading types; in terms of immediate use, the blood sample placement on the cards is a somewhat bulky process. Though there is no provision for subgroups (A1, A2, A1B & A2B) and other rare groups like the Bombay blood group, the immediacy of the results (within two minutes) for most patients provides significant value. Priced at USD 1.50 per test, the EldonCard is cost-effective, though comparisons with other rapid diagnostic tools like malaria tests suggest room for further price optimization. Post-use disposal introduces a slight challenge, as standard biohazard waste protocols need to be available; however, test results remain readable for years and may be preserved via an image scan or an included plastic cover as needed. The EldonCard's straightforward, portable design and reliability make it an appropriate and innovative choice for regular, low-cost blood typing.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: This technology is protected by trade secret. To use this technology, authorization from the patent owner or the assignee is required. Other intellectual property rights are likely to exist.

Local production: The device is compliant with relevant regulatory requirements including a compliant manufacturing process. Local production is less likely to bring further cost reduction to the product, however, the product has a moderate business case for local production especially if the local government has included such tests as part of EDL. The materials required are import-dependent for LMICs, but semi-finished materials can be partially manufactured in the regions. The manufacturing process needs controlled and dust-free facilities including clean rooms and equipment such as sterilizers.

Commercially available

Infant warmer*

Country of origin | Viet Nam

Primary use | Treatment/resuscitation/palliative care/surgery

Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 1900

Year of commercialization: 2018

Number of units distributed: 785

Currently marketed in: Benin, Burkina Faso, Sierra Leone, Ghana, Gambia, Indonesia, Iraq, Jamaica, Kenya, Cambodia, Lao People's Democratic Republic, Myanmar, Mozambique, Malawi, Malaysia, Namibia, Niger, Nigeria, Nepal, Philippines, Singapore, Togo, Thailand, Timor-Leste, United Republic of Tanzania, Uganda, Viet Nam, Zambia and Zimbabwe

Model: Wallaby

Product description

The Wallaby Warmer is designed to provide a controlled source of warmth to babies in the first weeks of life. The warmers can provide complete care for the newborn baby from the delivery through to the critically ill baby in neonatal intensive care.

Product details

Accessories: none

Consumables: none

Warranty duration: 2 years

Lifetime: 7 years

Energy requirements: 100-240VAC, 47-63Hz

Facility requirements: None

Contact: Gregory Dajer | Phone: +84 24 37 666 521 | Web: https://rb.gy/2zj7m6

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

Hypothermia is a cause of neonatal morbidity and mortality. Neonates are at high risk for hypothermia due to an increased surface-to-mass ratio as well as immature thermoregulation. Preterm neonates are at increased risk, making adequate thermal care essential to their initial resuscitation and care.

This technology provides a comprehensive answer to the problem of thermal care. Radiant heat is delivered by the overhead heating element, and the neonate is placed on an insulated mattress that minimizes heat loss. Skin temperature is monitored through a standard skin sensor and a remote temperature sensor as a backup. The device allows for automated control of energy output to optimize power usage, and the electronic display has several timers to assist in resuscitation. The device allows integration of other equipment used during resuscitation and serves as an X-ray bed.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Compliant (some requirements to be clarified).

The manufacturer provides a link to the available technical documentation. WHO has a technical specification document available (last modification applied in 2014) for infant warmers that can be used to compare the technical requirements of the proposed technology to assess their compliance.

Based on the technical data analyzed and compared, the technology can be considered compliant with the available WHO technical specifications, with the exception of the following minor requirements, which, while not strictly determinant for the compliance assessment result of the technical specifications, may be brought to the manufacturer's attention for clarification:

- The device can be operated by both a timer and skin temperature regulation;
- Table tilting capabilities for Trendelenburg and inverse Trendelenburg positions;
- Height-adjustable equipment and a height range are available.

Regulatory

Pre-market assessment	Proceed
Post-market assessment	Proceed with caution
Quality system assessment	Proceed
Security	Proceed

Pre-market: This product is a Class IIb medical device. The manufacturer has provided validation reports: IEC60601-1 and IEC60601-1-2. The software validation report IEC62304 and the IEC 60601-2-21:2009 specific safety requirements for the infant warmer test report are not available. A biocompatibility test based on ISO10993 has been provided. A clinical evaluation has been conducted, but a full report is not available.

Post-market: The manufacturer submitted post-market studies, ongoing post-market reports, and records of customer complaints. All regulatory approvals, including market authorizations, are not supported by documents; however, the Malaysian MDA website states that the product has been registered. The field safety corrective action plan and recall procedure documentation were not submitted.

Quality management system (QMS): The manufacturer has submitted an ISO13485:2016 certificate valid until 13 December 2023. Based on the certification and standards for performance, the product is safe and effective.

Security: The manufacturer submitted the risk analysis, risk management plan, risk control, post-production information, and protection against excessive temperature, and other hazard reports. The risk management report demonstrates that risk management activities carried out during the development and manufacturing of wallaby warmers are compliant with EN ISO 14971:2012. The introduction of this technology does not pose a biosecurity risk. The software validation report based on IEC62304 was provided to demonstrate the product is safe, effective, and cybersecure.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical		
Safety		
Economy		
Organizational		
Legal		
Social		
Ethical		
Green environment		

The product features a lower price and power consumption, though being as effective as the SoC products. It is CE certified, and the innovator has submitted a comprehensive suite of validation reports, affirming compliance with all essential standards for general safety and electromagnetic compatibility, alongside a software validation report ensuring the product's cybersecurity integrity. Notably, the report specific to the safety requirements for infant warmer tests, as stipulated by IEC 60601-2-21, is absent.

Furthermore, the innovator has conducted and presented a biocompatibility test, ensuring the product's biological safety and holds an ISO 13485:2016 certification, and the risk management, as documented in the related report, aligns with the EN ISO 14971:2012 standard. Collectively, the provided documents support the product's safety and reliability for clinical use. The device cost is listed as 1900 USD, so the device may be considered cost-effective. The Innovator's statement that the delivery costs are lower due to compact packing allowing savings on transportation fees is fully supported by the packaging validation report, which also proves the reliability of packaging design and materials, thus providing reliable protection to the device during storage and transportation to any location. The product does not use consumables and features cheap and widely available spare parts as stated by the innovator, which makes it particularly suitable for low-resource settings.

Technology readiness level 9

Technology evidence assessment Recommend with caution

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The MTTS Wallaby provides safe and automatic control of patient temperature, incorporates smart problem detection, and features an intuitive control panel with a clear LCD display for enhanced functionality and clinical performance. The device's energy efficiency and comprehensive safety alarms are tailored for global accessibility and cost-effectiveness, including low initial costs. A significant advantage for low resource settings is the ease of accessing internal components for repair and maintenance, coupled with the affordability and availability of spare parts. This design consideration facilitates timely and efficient servicing. However, the Warmer's touchscreen interface, while designed for straightforward navigation, may pose challenges in environments with limited digital literacy or under adverse environmental conditions. Additional considerations include the need for a reliable power supply and the importance of adequate staff training.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: The embedded software is proprietary. A clearance is required to use this technology.

Local production: Current regional volumes are low, manufacturing and technology are already in an optimal cost environment, and the final product is in the form of a semi-knocked-down kit. However, generating advantages through local production can be challenging.

WHO guidance

- Thermal Control of the Newborn: a practical guide. (2017). https://iris.who.int/bitstream/handle/10665/63986/WHO_RHT_MSM_97.2.pdf?sequence=1
- WHO recommendations on newborn health: guidelines approved by the WHO Guidelines Review Committee. (2017). https://iris.who.int/bitstream/handle/10665/259269/WHO-MCA-17.07-eng.pdf?sequence=1
- WHO recommendations for care of the preterm or low birth weight infant. (2022). https://iris.who.int/bitstream/handle/10665/363697/9789240058262-eng.pdf?sequence=1

Commercially available

Newborn ventilation trainer*

Country of origin | China
Primary use | Healthcare provider education and training
Category | Training manikin

Commercial information

List price (USD): 285*
Year of commercialization: 2023
Number of units distributed: 400
Currently marketed in: Globally
Model: NeoNatalie Live - Newborn Ventilation Trainer

* Not-for-profit price for SDG3 qualifying countries
https://tinyurl.com/ycx62jp5

Product description

NeoNatalie Live is a smart manikin that enables short and flexible training in newborn ventilation.

Together with a complementary app, NeoNatalie Live allows health workers to practice ventilation skills on their own. The manikin and app also enable newborn resuscitation team training and scenarios aligned with WHO´s Essential Newborn Care Course and the Helping Babies Breathe program.

Product details

Accessories: NeoNatalie Live includes the manikin itself (with user guide, baby cap, blanket, USB charger and cable), and the accompanying app to be downloaded from AppStore/GooglePlay. Products like Upright (with/without PEEP – 25 USD/30 USD), NeoBeat (190 USD) and mobile devices may be purchased separately to be used together with NeoNatalie Live.

Consumables: None

Warranty duration: 1 year

Lifetime: Shelf life is 3 years (if properly stored and maintained). It is advised to charge the device occasionally during long time storage.

Energy requirements: 110-240 VAC, 50/60Hz input power wall socket.

Facility requirements: Wifi is required when downloading the NeoNatalie Live app for first use.

Contact: Marita Sirevaag | Phone: +47 941 62 100 | Web: https://rb.gy/j5f99n

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

This technology is intended to train healthcare professionals on newborn ventilation. The manikin simulates four different patient cases and provides real-time training performance feedback through a complementary app that debriefs on each training session. The app also enables newborn resuscitation team training.

Overall, this technology is very useful in effectively training healthcare professionals, particularly in LMICs, where simulation-based education can be limited or absent.

** This assessment was initiated November 2023

Comparison with WHO technical specifications

Compliant.

The manufacturer provided the necessary detailed technical specifications, also supporting their declarations with the requested technical documentation (user guide or manual). In particular, WHO has a recent publication ("WHO neonatal resuscitation manikin: technical specifications. Geneva: World Health Organization; 2021 (WHO medical device technical series")) that can be used to compare the technical requirements provided. Following the release of the WHO technical specifications, WHO has issued additional guidelines regarding new born resuscitation, which eliminate the necessity for chest compressions in neonates. Consequently, the technology can be considered "compliant" with the existing WHO technical criteria and practical guidelines based solely on the stimulation and positive-pressure ventilation actions.

Regulatory

Pre-market assessment	N/A	Not applicable
Post-market assessment	N/A	Not applicable
Quality system assessment	N/A	Not applicable
Security	N/A	Not applicable

This product is not a medical device, and hence it is not applicable to assess it based on medical devices regulatoy requirements. .

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	N/A	
Safety	N/A	
Economy	!	
Organizational	→	
Legal	→	
Social	→	
Ethical	→	
Green environment	!	

NeoNatalie Live is a smart manikin that enables short and flexible training on newborn ventilation. Some early results of the provided evidence show promising outcomes from the implementation of the technology. It simulates various patient cases and provides objective performance feedback to help build competence and confidence in health workers. NeoNatalie Live system increased training frequency, staff participation, and ventilation quality. This device serves as a critical learning experience and opportunity to practice clinical assessment, decision-making and the execution of interventions.

Repeated practice may also improve provider comfort in managing such high-pressure scenarios independently. However, advantages compared to other solutions that could be employed in the same task should be discussed in detail. Although it is sold for a not-for-profit price for eligible LMICs, only preliminary cost-effectiveness studies exist, showing its cost effectiveness is largely dependent on the scaling and region of its implementation.

Technology readiness level 9

Technology evidence assessment Recommended with caution

Health technology management

Durability	N/A
Ease of Use	N/A
Ease of maintenance	N/A
Environmental conditions	✓
Affordability	!
Local access to technical support	!
Ease of cleaning	N/A
Infrastructure requirements	!

Health-care delivery platform

The NeoNatalie Live is designed to mimic the real-life responses of a newborn, such as variable heart rates, respiratory rates, and crying, providing a realistic platform for training in neonatal resuscitation and other essential newborn care skills. No durability or chemical resistance testing was uploaded. Preventive maintenance required is basic; corrective maintenance is undefined. The manufacturer is working on the development of a service repair program that will make spare parts available. At 285 USD, NeoNatalie Live is a significant investment, especially for training institutions with limited budgets and health facilities trying to implement on-the-job orientation programs with already stretched budgets.

Although this price point is lower than many options for simulation mannequins on the market, balancing cost and functionality is key to making it accessible to a broader range of users. More extensive testing of usability, durability, chemical resistance, and market need is required before the product can be effectively recommended for scale. As the product works using an app, infrastructural requirements for mobile devices should also be considered.

Intellectual property and local production

Technology transferability	!
Open source/ access	🔒
Local production	⛔

Intellectual property: The product is protected by copyright, trade secrets, and trademarks. A clearance is required to use this technology.

Local production: The business case is weak if this product alone is considered for local manufacturing: volumes are low, required materials are import-dependent, the skill required is high, added manufacturing and technology are already in an optimal cost environment, and the final product is in the form of a semi-knocked-down kit.

WHO guidance

- WHO Essential Newborn Care Modular Course. (2022). https://cdn.who.int/media/docs/default-source/mca-documents/nbh/enc-course/modules/11-facilitator-notes-kangaroo-mother-care-16.03.22.pdf?sfvrsn=ab181d02_5
- Managing Complications in Pregnancy and Childbirth: A guide for midwives and doctors. (2017). https://iris.who.int/bitstream/handle/10665/255760/9789241565493-eng.pdf?sequence=1
- WHO neonatal resuscitation manikin technical specifications (2021). https://www.who.int/publications/i/item/9789240031333
- WHO Technical specifications of Neonatal Resuscitation Devices (2016). https://www.who.int/publications/i/item/9789241510264

Commercially available

Patient monitoring system*

Country of origin | United States of America
Primary use | Diagnosis/measurement/monitoring
Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 275
Year of commercialization: 2021
Number of units distributed: 214
Currently marketed in: Ghana, Kenya and Uganda
Model: 1

Product description

The Neopenda neoGuardTM is a patient monitoring system consisting of the following components: wireless sensor devices, reusable wearable bands, and a software application that receives, displays, and stores data from the sensor devices. The sensor devices use a reflectance pulse oximeter and temperature sensors to measure the pulse rate, blood oxygen saturation (SpO2), respiration rate, and temperature of the patient. The neoGuard devices are attached to the patient's body by reusable wearable bands and are battery-powered. The devices transmit data using low-energy Bluetooth® in a localized communication architecture. Data is received by a software application installed on a tablet.

Product details

Accessories: Sensor device charging cable: GlobTek microUSB GTM96060-0606-1.0, or equivalent, Tablet charging cable: Samsung Galaxy Tab A 10.1" 32GB SM-T510NZKAXAR, or equivalent, Wall plug adapter for tablet charging cable: Ceptics IG-7, or equivalent, Tablet case: Poetic Samsung Galaxy Tab A 10.1 case, or equivalent, Security cable: Ruiwor RW0202 locking cable, or equivalent, Instructions for use, Quick guide

Consumables: 70-90% isopropyl alcohol cotton

Warranty duration: 2 years

Lifetime: 2 years - equivalent to maximum 17 110 hours of monitoring, approximately 292 cycles of battery recharging, and approximately 1460 cycles of stretching the band (twice per day)

Energy requirements: Medical grade (2 x MOPP from input to output according to EN 60601-1:2006), Input (AC): 100–240 V, 50–60 Hz, Output (DC): 5 V, 1.5 A

Facility requirements: Electricity supply for charging and recharging the neoGuard device

Contact: Sona Shah | Phone: +1 91 962 22487 | Web: https://rb.gy/7fqd6r

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

This product is for non-invasive continuous monitoring of blood oxygen saturation (SpO2), pulse rate (PR), respiration rate (RR), and temperature. It is composed of a wearable band to put around the head where the sensor device is connected, and measurements are taken on the forehead. It is designed for low-resource settings, and it works without the internet as the devices transmit the information to the central interface via Bluetooth.

This technology improves patient monitoring, especially in low-resource settings. It is easy to operate and allows centralized monitoring of many patients at the same time.

** This assessment was initiated November 2023

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer provides the necessary detailed technical specifications, along with technical documentation (that is instructions and user manual) supporting their declarations. Since even the most basic WHO available technical specifications document related to patient vital signs monitors will include the NIBP (Non-Invasive Blood Pressure) measurement and this parameter is not monitored by the proposed technology, at the time of this report creation, WHO similar device technical specifications are not available to compare this type of technology which is an equipment specifically dedicated to monitoring just only the patient SPO2, temperature, respiratory and pulse rates.

Regulatory

Pre-market assessment	Proceed
Post-market assessment	Proceed with caution
Quality system assessment	Proceed
Security	Proceed

Pre-market: The product has obtained market approval in Kenya. The manufacturer has shared the design verification and validation test report list and the reports. Based on the certification and standards for the performance of this device, the documentation submitted is adequate to demonstrate that the product is safe and effective.

Post-market: The manufacturer declared that they have some of the post-market documentation but did not submit the post-market surveillance and vigilance documentation. According to the submission, there have been no recalls or adverse events reported. Nevertheless, it is considered good regulatory practice to establish the complete PM system before introducing the product to the market.

Quality management system (QMS): The manufacturer site has valid ISO13485:2016 certification for the manufacturing of the product. Based on the certification and standards, the manufacturing of the product conforms to ISO13485:2016 and the performance of the product is safe and effective.

Security: The manufacturer has declared conformance to IEC62304 software validation for the lifecycle of the device and hence addressed the cybersecurity risk. The manufacturer has submitted risk management documentation, including the risk analysis, risk management plan, risk control, post-production information, and other hazard reports.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical		
Safety		
Economy		
Organizational		
Legal		
Social		
Ethical		
Green environment		

This wearable monitoring device, utilizing two non-invasive sensors, offers advantages for both patients, especially newborns, and healthcare providers in resource-limited settings. It allows real-time monitoring and visualization of four vital signs for up to 15 patients, potentially reducing the detection time for deteriorating patients, enabling faster treatment initiation, and decreasing mortality rates, particularly in neonatal care. The device has undergone rigorous validation in phases 1, 2, and 3 clinical trials, demonstrating safety, feasibility, and effectiveness without reported adverse events. Developed with robust risk management protocols, it conforms to EN ISO 14971:2019 standards.

While compact and cost-effective, further research is ongoing to optimize its performance and assess its cost-effectiveness in comparison to standard care equipment. Feasibility studies indicate general patient acceptance, with minimal withdrawal of consent by parents of monitored newborns. Its reduced size and efficiency in monitoring multiple vital signs suggest increased sustainability by minimizing equipment idle time.

Technology readiness level 9

Technology evidence assessment Recommended

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The neoGuard system is a multiparameter neonatal monitoring device with a patient-specific sensor and a tablet-based central monitoring server. 15 NeoGuard sensors can be used with a single monitoring server. Operationally, the sensor is placed on the forehead of each newborn patient requiring monitoring. While this non-traditional placement might offer certain technical advantages, practical challenges related to skin sensitivity, movement, access, interference with other equipment, and infant comfort make it a less favorable option in neonatal care. The tablet-based user interface is underdeveloped and would benefit from further UX improvement.

The manufacturer also advises against opening or repairing the device, emphasizing the need for manufacturer-only maintenance and software updates; as a tablet-based system, the maintenance and durability elements of any tablet will also contribute to the longevity of the product. Cleaning the device is straightforward; the manufacturer has provided clear guidelines for cleaning using isopropyl alcohol. Although the initial unit cost for the sensors is reasonable for a multiparameter device, the cost for long-term maintenance of the software, server, and tablet is not clear. NeoGuard presents a solution for a much-needed centralized neonatal monitoring system but faces challenges with usability and maintenance.

Intellectual property and local production

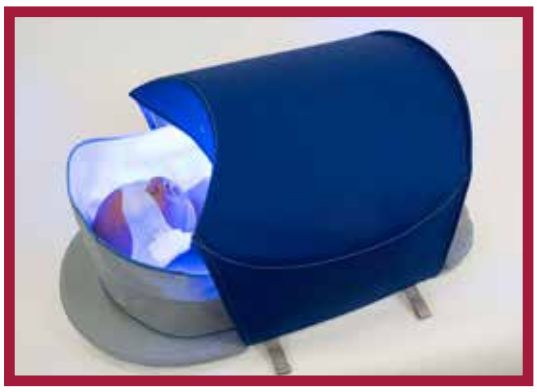
- Technology transferability
- Open source/ access
- Local production

Intellectual property: This technology uses proprietary software. The technology is protected by patents, trademarks and copyrights, however, there are pending patents. The use of all intellectual property will require clearance.

Local production: The product has a compliant manufacturing process. The technology has a moderate business case in end-to-end production as the technology is highly import-dependent, key manufacturing know-how is likely to be with the contract or licensed manufacturers, and a comparatively high level of technical and quality control expertise and related infrastructure is required. However, the SKD approach can be considered for local production with an anticipation of low volumes until the technology is widely accepted in the region.

Commercially available

Portable, high-intensity neonatal LED phototherapy*



Country of origin | United States of America

Primary use | Treatment/resuscitation/palliative care/surgery

Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 2500

Year of commercialization: 2020

Number of units distributed: 250

Currently marketed in: Indonesia, Kuwait, Mongolia, Malaysia, United Arab Emirates and United States of America

Model: bili-hut global™

Product description

Ultraportable, high intensity LED phototherapy for the treatment of neonatal hyperbilirubinemia (jaundice)

Product details

Accessories: phototherapy swaddling garment (optional); bassinet cart adapter ("perch")

Consumables: both reusable or disposable positioning "nest" options for infant are available

Warranty duration: 3 years

Lifetime: 5 years

Energy requirements: 90-264 VAC 50/60 Hz

Facility requirements: Approved for hospital use. It may be set up at mother's side on a table, cart, trolley or crib.

Contact: Donna Brezinski, MD | Phone: +1 78 172 52460 | Web: https://rb.gy/g10r9c

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

Neonatal hyperbilirubinemia is a common occurrence in neonates, as the immature liver is unable to adequately metabolize bilirubin. High serum levels of bilirubin lead to its deposition in the skin, mucosae, and sclerae, thus manifesting as jaundice. Bilirubin may also be deposited in the central nervous system, predominantly in the basal ganglia. If left untreated, this may lead to severe neurological impairment and death.

The standard of care for this condition is phototherapy which breaks down circulating bilirubin into molecules that can be excreted without hepatic metabolization. As the newborn's liver matures, it can adequately metabolize and excrete bilirubin and the phototherapy can be discontinued.

Despite being standard of care, the effective application of phototherapy in low-resource settings has been hindered by the medical devices used. Issues with size, transportability, robustness, and energy consumption have led to limited access to treatment across the globe. This technology attempts to overcome these limitations, greatly increasing treatment coverage while maintaining the standard for the adequate care of this condition.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

The user manual provided is well detailed and it reports accurately the technical details. A technical brochure would give a better view of technical details but it is not strictly necessary in this case since the provided technical documents are complete. UNICEF has technical specifications available for a "Mobile LED phototherapy unit AC powered", but this is not a cot-shaped device but a mobile lamp. At the time of report creation, WHO phototherapy / hyperbilirubinemia / jaundice lamps or unit technical specifications were not available to compare the specific requirements of this type of technology.

Regulatory

Pre-market assessment	Proceed
Post-market assessment	Proceed with caution
Quality system assessment	Proceed
Security	Proceed with caution

Pre-market: This product is a Class IIa medical device and has obtained market approval in UAE, Indonesia, Kuwait, Mongolia, Malaysia, and the USA. Based on the certification and standards for the performance of this device, the documentation submitted is adequate to demonstrate the product is safe and effective.

Post-market: The manufacturer submitted partial post-market surveillance and vigilance documentation. According to the submission, there have been no recalls or adverse events since the release of Bili Hut. Nevertheless, it is considered good regulatory practice to establish the PM system before introducing the product to the market.

Quality management system (QMS): The manufacturer has submitted a valid ISO13485:2016 which is valid until 15 July 2025. Based on the certification and standards for performance, the product is safe and effective.

Security: The manufacturer did not submit the risk management documentation, which is crucial to ensure safety and performance of the device.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	→	
Safety	→	
Economy	→	
Organizational	!	
Legal	→	
Social	→	
Ethical	→	
Green environment	!	

The device stands out due to its innovative design, featuring a curved, flexible canopy equipped with LED lights. This design provides multidirectional illumination, covering approximately 50% more skin area than standard of care (SoC) devices. It boasts a simple, collapsible structure, weighing under 4 kg and having a compact size, making it easy to store and transport in a carrying case. This portability allows it to be conveniently set up next to the mother in a hospital. Its semi-enclosed design helps to minimize heat loss, often removing the need for an incubator during treatment for most infants, and prevents light leakage into the surrounding area.

The device is safe, not posing any additional risks compared to SoC devices, and adheres to all relevant safety standards. The innovator manages risks in line with ISO 14971:2019 and upholds quality management according to ISO 13485. This technology has been utilized in various clinical settings worldwide for over three years without any reported adverse events.

It has proven to be highly reliable and effective, even under challenging conditions, with treatment times typically less than two days for nearly all patients, surpassing other SoC devices. This makes it particularly advantageous for low-resource areas where jaundice is more prevalent.

Technology readiness level 9

Technology evidence assessment Recommended

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The bili-hut is a specialized neonatal phototherapy device designed to provide 180° light coverage in a portable, lightweight package with an enclosed design to prevent patient heat loss. However, this enclosure design may obstruct constant patient visibility necessary for nursing staff in hospitals. Though this may be less of an issue in one-on-one home care, the device's 2500 USD cost significantly restricts its accessibility in both health-care facilities and for home use in low-resource settings (LRS); home use is impractical unless health facilities are sufficiently organized and supported to offer such devices on a borrowed term for home treatment.

A notable concern is the device's recommended room temperature range of 70°F to 76°F (21.1°-24.4°C), which is quite narrow and more suited to controlled home settings. This temperature requirement is challenging to maintain in many areas where neonatal jaundice demands are the highest due to varying climate and infrastructural constraints. While the bili-hut is innovative and effective in treating jaundice and significant effort has been dedicated to testing usability and durability, its practicality in LRS hospital and home contexts is limited.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: It is patent-protected. To use this technology, authorization from the patent owner or the assignee is required.

Local production: Product design is advantageous for moderate to high-volume manufacturing. Moderate cost reduction can be achieved through local manufacturing. Local production is promising only for regions or markets with consistent, high annual product demand.

WHO guidance

- WHO recommendations on newborn health: guidelines approved by the WHO Guidelines Review Committee. (2017). https://iris.who.int/bitstream/handle/10665/259269/WHO-MCA-17.07-eng.pdf?sequence=1

Commercially available

Smart eye camera attached to a smartphone*

Country of origin | Japan

Primary use | Diagnosis/measurement/monitoring

Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 1000

Year of commercialization: 2021

Number of units distributed: 250

Currently marketed in: Belgium, Cambodia, Germany, Japan, Kenya, Spain and Viet Nam

Model: Smartphone attachment medical device

Product description

Smart Eye Camera (SEC) is a smartphone attachment medical device that uses the light source and camera function of the smartphone, enabling it to observe the anterior segment of the eye with equal function to the conventional slit-lamp microscope. By attaching the SEC to a smartphone, the user can observe the eyelid, cornea, anterior chamber, iris, lens, and vitreous body, as with existing slit-lamp microscopes, and diagnose ophthalmic diseases such as cataracts.

Product details

Accessories: The device is applicable to iPhone 7/8/SE2/SE3. The device is delivered with the applicable phones with the software (SEC App) installed and the charger of the iPhone and the hard-case for the device.

Consumables: n/a

Warranty duration: 2 years

Lifetime: 5 years

Energy requirements: No. No need for external battery as long as the phone is charged.

Facility requirements: Please store in the attached case in a stable place. Carry by putting it in the attached case. Store under the following environment: Temperature: 4-35°C; Humidity: 30–80% RH (no condensation of moisture); Atmospheric pressure: 800–1060 hPa; Avoid direct sunlight, store at a place away from any liquid; store away from flammable fumes/liquid.

Contact: Shintaro Nakayama | Phone: +81 80 3014 8440 | Web: https://rb.gy/xqrjcl

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

Preventable blindness is one of the major public health challenges faced today. In low-resource settings, access to adequate ophthalmic care is hindered by the low availability of adequate equipment and trained professionals, delaying diagnosis and referral.

The slit-lamp microscope is an essential tool in ophthalmic examination. However, it is a cumbersome, sensitive, and costly piece of equipment. Moreover, most slit-lamp microscopes cannot acquire images (photography or video).

This technology simplifies several aspects of the slit-lamp microscope examination. It is a compact device that transforms a smartphone into a device capable of performing a comprehensive examination of the anterior structures of the eye. Through the smartphone's capabilities, it is also possible to record and transmit videos to other health-care professionals at different locations. This device has been field-tested for use in the diagnosis of dry eye disease and cataracts. It may also assist in the diagnosis of trachoma, traditionally diagnosed with the use of loupes.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

This medical device is an ophthalmic camera that is applied to mobile phones to diagnose specific ophthalmic clinical issues. A slit lamp, whose specifications are not included in any technical requirements document, WHO or UNICEF catalogues, is the medical equipment with the more comparable technical requirements. Consequently, at the time of this report creation, WHO and/or UNICEF technical specifications were not available to compare this type of technology.

Regulatory

Pre-market: This product is a Class I medical device in Japan and has obtained market approval in Cambodia, the EU, Japan, Kenya, Viet Nam and Swissmedic Class I notification. However, the manufacturer did not provide adequate documentation for a regulatory review, including the design verification reports and the validation test reports lists.

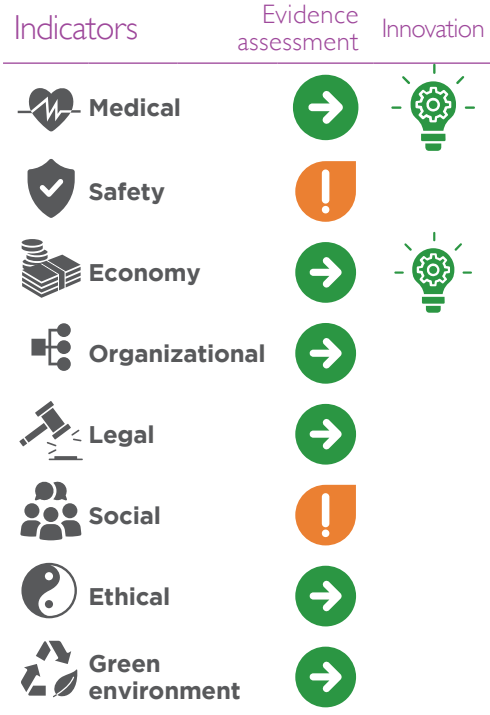
Post-market: The manufacturer did not submit surveillance and vigilance documentation, complaint handling, field safety corrective action, recall, or adverse event reporting documents.

Quality management system (QMS): The manufacturer has submitted a valid ISO13485:2016 which is valid until 13 June 2026. Based on the certification and standards, the manufacture of the product conforms to ISO13485:2016. Based on the certification and standards for the performance of this device, the documentation submitted is not adequate to demonstrate that the product is safe and effective.

Security: Introduction of this technology would not lead to cybersecurity or biosecurity risk. The manufacturer did not submit risk management documentation, risk analysis, risk management plan, risk control, post-production information, or other hazard reports.

Adequate documentation was not provided to perform a medical device regulatory premarket, post-market, quality system, and security review and assessment on the product to demonstrate that the product is safe and performs as intended by the manufacturer.

Health technology assessment



The technology is non-invasive and uses the light source and the camera of a smartphone to deliver ophthalmic diagnosis, while not introducing any additional safety risk. However, although the innovator claims that the product is CE-certified, the documentation provided does not prove that. The two certificates provided, for risk and quality management, are issued to another company and not to the innovator, and it is not clear how the two companies are related. Despite the insufficient evidence, the technology may be considered safe, as there are no apparent reasons to the contrary. The associated risks are low, especially because it does not require an external power supply. The expected clinical benefits are high since it will enable non-ophthalmologists, nurses, and other health-care workers with no specific experience in ophthalmology to take good-quality ophthalmic images that can satisfy professional ophthalmologists, just after a short tutorial session. It is expected to play a critical role in improving the standard quality of ophthalmic services. The device is 80-90% less expensive than a conventional slit-lamp microscope and can extend the reach of accessible eye care.

Technology readiness level 9

Technology evidence assessment Recommend with caution

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

This product is app-based, with a base technology that is known and easy to use for everybody and requires use of proprietary 3D printed hardware and a commercially available iPhone. Currently, it is only available for IOS. It is 4-5 times more affordable than the standard of care technology. It is designed for basic ophthalmologic diagnosis in low-resource settings, allowing real-time contact with specialists when necessary, and does not require the heavy, expensive technology for routine eye checks.

Durability depends on the phone hardware. Because of the SEC lens attachment, a phone protective case cannot be used, and the device should be safely stored in the included storage case when not in use. Preventive maintenance is easy to provide to the supplied SEC hardware, and suppliers can be contacted electronically for support and parts. The phone requires maintenance at a specialized phone maintenance shop, which is usually easily available. Also, the manufacturer can provide repairs on the phone. Reparability does not only depend on the supplier, but also the phone manufacturer; the device will work properly as long as Apple keeps parts available. The supplier should keep their software up-to-date with IOS new releases to avoid crashes.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: This technology is protected by copyright, patents and registered trademarks. Some patents are pending, and trade secrets are likely to exist. The use of all intellectual property will require clearance.

Local production: Only the SEC slit lamp attachment is considered (the mobile phone is excluded from the scope of evaluation for local production).

This is a potential product for local production. Although the company has product patents, there is insufficient evidence to ensure the manufacture of a safe medical device such as a fully compliant product design procedure and a fully compliant ISO 13485 QMS is not available. Further, low regional market demand, dependence on imported raw materials, machinery, and 3D Printer utilization scenario are unlikely to justify the business case for local production of this technology.

Commercially available

Smartphone application for blood pressure monitoring*

Country of origin | Switzerland
Primary use | Diagnosis/measurement/monitoring
Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 5
Year of commercialization: N/A
Number of units distributed: 0
Currently marketed in: Austria, Bangladesh, France, Germany, Ghana, Kenya, Rwanda, South Africa, Switzerland and United Republic of Tanzania
Model: OptiBP™

Product description

Biospectal OptiBP uses cuff less blood pressure measurement using a fingertip on a smartphone camera along with optical algorithms on smartphones, transforming the device into an easy-to-use, accurate blood pressure monitor to manage hypertension, the silent killer and number one chronic health condition worldwide.

Product details

Accessories: N/A
Consumables: N/A
Warranty duration: N/A
Lifetime: Annual software updates, but lifetime value
Energy requirements: Mobile phone
Facility requirements: N/A

Contact: Natalie Meyer | Phone: +1 80 237 71977 | Web: https://bit.ly/45RfzRg

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical — Recommended with caution

Hypertension affects 1.3 billion people globally and is the leading risk factor for cardiovascular, cerebrovascular and chronic kidney disease. According to the most recent WHO Global Hypertension Report (2023), about 78% of adults with hypertension live in LMICs. Globally, an estimated 54% of patients have been diagnosed with hypertension, and just over a fifth of them have had their blood pressure controlled.

This technology uses a smartphone camera to measure blood flow at the fingertip, which is analysed by photopletismography. Blood pressure is estimated from a specific algorithm, and initial calibration is performed with a standard blood pressure cuff. The device has been extensively tested in different settings (including LMICs) and different populations across the globe. Results have been encouraging and have validated the device's use in non-pregnant adults. Dissemination of this technology can facilitate blood pressure control in low-resource settings. Currently, OptiBP only works with a limited list of compatible Android smartphones. New models are regularly tested and included on the supported device list.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer has provided detailed technical documents, including the user manual in English. At the time of this report creation, WHO did not have any technical specifications document available to compare this software application for blood pressure monitoring.

Regulatory

Pre-market assessment	Proceed with caution
Post-market assessment	Proceed with caution
Quality system assessment	Proceed
Security	Proceed with caution

Pre-market: This product is a class IIa medical device in the EU. The manufacturer declared that they have the design verification and validation of the product but did not submit these documents. Consequently, full premarket assessments could not be conducted to ensure the safety and performance of the product.

Post-market: The manufacturer declared that they have post-market documentation but did not submit the post-market surveillance and vigilance documentation. According to the submission, there have been no recalls or adverse events since the release of the product. Nevertheless, it is considered good regulatory practice to establish the PM system before introducing the product to the market.

Quality management system (QMS): The manufacturer has submitted a ISO13485:2016 valid until 17 January 2024. Based on the certification and standards for performance, the product is safe and effective.

Security: This technology could introduce a cybersecurity risk. The manufacturer did not submit risk management or information documentation on security management systems to ensure the safety and performance of the device.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	→	✓
Safety	→	✓
Economy	!	✓
Organizational	!	✓
Legal	→	
Social	→	
Ethical	→	
Green environment	→	✓

The technology enhances health outcomes by promoting better user adherence and integrating connected data with clinicians. Concurrently, it reduces costs by eliminating the necessity for supplying blood pressure cuffs in vulnerable health systems, while delivering the same quality as a medical-grade blood pressure cuff. Moreover, leveraging the extensive data collected through OptiBP can offer unprecedented epidemiological insights at a global scale.

Technology readiness level 9

Technology evidence assessment Recommended

Health technology management

- Durability: N/A
- Ease of Use: →
- Ease of maintenance: N/A
- Environmental conditions: →
- Affordability: →
- Local access to technical support: →
- Ease of cleaning: N/A
- Infrastructure requirements: N/A

Health-care delivery platform

This smartphone app uses the phone's camera to detect and measure blood pressure and heart rate. It can be used on any smartphone. It needs to be calibrated with a sphygmomanometer, hence involvement of a health-care practitioner is required to begin. The app is easy to use and can serve both patients and health-care practitioners. The durability, ease of maintenance, ease of cleaning and infrastructural and environmental requirements depend on the phone used. The app is independent of those factors. Technical support is available through the app. The affordability will depend on the purchase price of the app but is estimated to be appropriate. Ownership of the phone and the app should be considered.

Intellectual property and local production

- Technology transferability: !
- Open source/ access: 🔒
- Local production: N/A

Intellectual property: This technology is protected by copyright and patents and has a registered trademark. The use of all intellectual property including any third-party-owned rights will require clearance.

Local production: This is a software algorithm.

Commercially available

Training for essential birthing manoeuvers*

Country of origin | China

Primary use | Healthcare provider education and training

Category | Training manikin

Commercial information

List price (USD): 555

Year of commercialization: 2021

Number of units distributed: 4700

Currently marketed in: Globally

Model: MamaBirthie CS Birthing and Safe C-Section Simulator

Product description

MamaBirthie CS is ideal for training in birthing assessment and can be used for basic skill acquisition and competency development for all stages of labour

Product details

Accessories: Placenta with umbilical cord and membranes, BabyBirthie newborn manikin, cervix inserts (4, 6, and 8 cm dilatation), USB with instructional videos, pinard stethoscope, table clamp, syringe, urine catheter, 2 blankets, 2 packs gloves, fetal fontanelle skull, carry bag, caesarian section uterus.

Consumables: N/A

Warranty duration: 1 year

Lifetime: 3 years shelf life

Energy requirements: N/A

Facility requirements: N/A

Contact: Karoline Linde | Phone: +47 51 51 17 00 | Web: https://bit.ly/3VJTol0

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

The technology is a birth simulator that enables health-care professionals to gain competency and confidence in vaginal and operative births. It can be used to train birth-assisting skills such as abdominal and vaginal examinations, normal birth, shoulder dystocia and vaginal breech.

It has a specific module to train in caesarian section and abdominal suturing (i.e., B-Lynch suture for postpartum haemorrhage).

Overall, this technology is significantly useful in training health-care professionals, from medical students, residents, and other doctors in training to nurses and midwives, particularly in LMICs, where simulation-based education can be limited or absent.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer provides the necessary detailed technical specifications, supporting their declarations with different technical documentation. At the time of this report's creation, WHO technical specifications documents were not available to compare this type of technology, while UNICEF has technical specifications for different childbirth simulators.

Regulatory

Pre-market assessment	N/A Not applicable
Post-market assessment	N/A Not applicable
Quality system assessment	Proceed
Security	Proceed

This product is not a medical device, and hence not applicable to assess it based on medical device regulatory requirements.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	→	
Safety	→	
Economy	→	
Organizational	→	
Legal	→	
Social	!	
Ethical	N/A	
Green environment	!	

The technology is an innovative birth and caesarean section simulator made of neoprene, polypropylene, and textile materials (lycra) without the need for electrical power. The product is safe, and the innovator has conducted quality management according to ISO13485 and ISO9001 and security management as per ISO/IEC 27001 with all relevant documentation provided.

The simulator can be used as a tabletop attachment or worn by the trainer, which is ideal for simulating reality in provider-client communication. It facilitates the practice of all essential skills required during birth and postpartum, such as abdominal and vaginal examination, normal childbirth, anatomical rotation at birth, assisted breech and vacuum delivery, shoulder dystocia, bladder catheterization, and B-lynch suture in the management of severe postpartum bleeding.

The product is intended for use in in-service training and pre-service education programmes of undergraduate medical doctors, obstetrics and gynaecology residents, non-physician emergency surgical officers, and comprehensive emergency obstetrics. It is highly suitable for basic skill acquisition and competency development for all stages of labour especially for caesarean section training; it is an indispensable, life-saving intervention for women and newborns who require, safe, prompt interventions. The simulator trains students in skills with case scenarios before entering clinical practice, significantly enhancing the quality of care they offer to patients. Adequate training contributes to competent and confident medical doctors, midwives, and nurses, ensuring access to safe caesarean section procedures in LMICs.

Technology readiness level 9

Technology evidence assessment Recommended

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

By providing safe, realistic simulations, the MamaBirthie can play a significant role in enhancing the skills and confidence of health-care providers, leading to improved maternal and neonatal outcomes. The manufacturer has completed durability testing, which indicated wear and tear on product fabrics after a set number of simulated caesarian sections were completed. The stage of improvement of the current product is unclear. No evidence of commonly used hospital chemicals resistance tests has been submitted.

Preventive and corrective maintenance training was not available in the manufacturer submission. Multiple beta tests for 'usability' testing were completed; however, detailed protocols for these tests have not been submitted. At 555 USD, the MamaBirthie is a significant investment, particularly for training institutions with limited budgets and health facilities trying to implement on-the-job orientation programmes with already stretched budgets. Although this price point is competitive with those of other products on the market landscape, continued price optimization is key to making it accessible to a broader range of users.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: This technology is protected by copyrights and trade secrets. The use of all intellectual property will require clearance.

Local production: The product has a compliant manufacturing process. Due to the import dependency of the raw materials and the low rate of growth of global requirements, the product has a moderate business case. As the product is currently manufactured in an optimal cost region, further cost reduction may be challenging.

Commercially available

Ultrasound imaging system*

Country of origin | United States of America
Primary use | Diagnosis/measurement/monitoring
Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 2699
Year of commercialization: 2019
Number of units distributed: 65 000
Currently marketed in: Argentina, Australia, Austria, Canada, Chile, Colombia, Denmark, Egypt, Finland, France, Germany, Iceland, India, Israel, Italy, Kenya, Kuwait, Netherlands (Kingdom of the), New Zealand, Norway, Oman, Pakistan, Poland, Portugal, Qatar, Saudi Arabia, South Africa, Sweden, Switzerland, Türkiye, United Arab Emirates, United Kingdom, USA
Model: Butterfly iQ+ Ultrasound Product System (850-20014)

Product description

The Butterfly iQ Ultrasound System is a hand-held, whole-body single-probe portable ultrasound system that is indicated for use by trained health-care professionals in environments where health care is provided to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids of adult and paediatric patients for the following clinical applications: peripheral vessels (including carotid, deep vein thrombosis, and arterial studies), procedural guidance, small organs (including thyroid, scrotum, and breast), cardiac, abdominal, urology, fetal or obstetric, gynaecological, musculoskeletal (conventional), musculoskeletal (superficial), and ophthalmic.

Product details

Accessories: Butterfly IQ + Ultrasound System 1.5 m cable USB-C, 2.5m cable USB-C, 1.5m cable lightning, 2.5m cable lightning, charger kit, holster, soft case, hard case, and hard case v2.
Consumables: Gel
Warranty duration: 1 year included, extended to 3 years with cost.
Lifetime: 5 years
Energy requirements: 110/220V for charger to be plugged into outlet.
Facility requirements: Electricity for charging probe at least intermittently, Wi-Fi if cloud use desired.

Contact: Sachita Shah | Phone: +1 855 296 6188 | Web: https://bit.ly/3VTBgvb

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

Point-of-care ultrasonography is emerging as a new standard of care. By bringing imaging to the bedside, patient examination can be enhanced. The technological advances that made it possible transformed the modern bedside ultrasound into a portable and robust device, allowing deployment in low-resource settings. The widespread availability of ultrasonography allows for better diagnosis and care of many conditions, such as cardiac, pulmonary, or obstetric and gynaecological conditions. Ultrasound guided procedures are safer and often have fewer complications.

This technology leverages the high rate of smartphone ownership to deploy advanced ultrasonography, with artificial intelligence (AI) tools that can assist less skilled operators in more advanced aspects of cardiac or obstetric and gynaecological examinations. Connection to a dedicated cloud service allows for remote proctoring of trainees or expert consults. Despite the AI assistance, operators still require training and proctoring, as AI algorithms still present limitations, and critical judgement is required to interpret results and make clinical decisions. A subscription-based business model may limit deployment in certain settings, as several of the innovative features offered are limited to the payment of a yearly subscription.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Compliant (with minor exceptions).

The manufacturer included in the submission form all the main technical specifications. They are well supported and detailed in the technical specifications sections included in the user manual. The technology proposed is composed of a multi-function ultrasound probe, a software application for portable devices, cloud services, and an optional cloud connector.

WHO has no technical specifications document related to exactly this kind of system, although a very similar technical requirements document (portable ultrasound scanner) can be used to compare only the specifications that describe the same features or characteristics.

Keeping in mind the aforementioned and after assessing the comparator outputs, the proposed technology can be considered compliant with the following exceptions, which might be considered minor since the compared technologies and systems are not identical:

- screen monitor of at least 25 cm;
- operates from an AC power electric line: 100-240V, 50/60 Hz;
- automatic switch AC power electric line/battery operating modes;
- data communication, storage, and transfer interface: USB minimum; zooming capability with automated image optimization;
- transducer ports: at least two active transducer ports permanently available;
- capability of switching between probes.

Moreover, the following applications are not available: intra-vascular, lung, and trans-vaginal.

Regulatory

Pre-market assessment	Proceed
Post-market assessment	Proceed with caution
Quality system assessment	Proceed
Security	Proceed

Pre-market: The product has obtained market approval in the EU. Certification and standards for performance, the documentation submitted is adequate to demonstrate that the product is safe and effective.

Post-market: The manufacturers declared that they have the post-market documentation but did not submit the post-market surveillance and vigilance documentation. According to the submission, there have been recalls, but no adverse events have been reported since the release of the product. They have declared that they have undertaken to resolve the recalls. However, these reports were not submitted for assessment of the safety and performance of the device.

QMS: The manufacturer has submitted risk management documentation and implemented the risk management process required in ISO14971.

Security: The manufacturer has declared conformity to IEC62304 software validation for the lifecycle of the device, which also addresses issues due to cybersecurity risk.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	!	✓
Safety	→	
Economy	!	
Organizational	→	✓
Legal	!	
Social	!	
Ethical	N/A	
Green environment	→	

This technology is an innovative design concept in the field of ultrasonography. Given its ergonomic design and a single probe, it can be easy to use and operated by naïve operators. However, it must be used under expert supervision to prevent any misdiagnosis or repercussions. The lack of post-market clinical follow-up represents a gap in continual data collection on device performance and safety.

Although priced lower than competitors, the manufacturer has the opportunity to standardize pricing that is based on health economics. For example, budget impact analysis performed using inputs from authentic sources rather than arbitrary assumptions may provide robust insights into the financial consequences of adopting this technology.

Although no major legal or ethical issues can be foreseen with this technology, it is imperative to use it judiciously without any violation of regulatory norms. Also, rigorous post-market clinical follow-up contributing to the safe and effective use of Butterfly iQ in the real world are recommended, particularly in light of recent product recalls.

Technology readiness level 9

Technology evidence assessment Recommend with caution

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The Butterfly ultrasound system is a universal ultrasound sensor with a tablet-based display. The tablet-based user interface is very well developed and makes it easy to annotate images; however, screen size and resolution are dependent on the connected device, which could impact image interpretation. Extensive technical support and training resources are available online, including access to international experts and video-based training. Cloud-based support is available, and devices can be integrated into existing electronic medical records systems. The system has been tested for military-grade durability and can endure drops of up to 1.2 m, electric shocks of up to 100G, and can resist dust and water (IP67). However, as it is a tablet-based system, the maintenance and durability elements of any tablet will also contribute to the longevity of the product. The Butterfly cloud network also integrates artificial intelligence and machine learning in multiple care pathways; systems are in place to enable consistent maintenance and updates for the Butterfly apps to ensure that as software and machine learning improve, users will have near-immediate access. Although the unit costs appear steep at 2699 USD for initial purchase, the comparable cost in this product landscape for the level of features available is reasonable. The Butterfly iQ is a significant step forward in making ultrasound technology more appropriate, accessible, portable and versatile.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: This technology is patent-protected and has registered trademarks. The use of all intellectual property will require clearance. The use of patented, compatible third-party products may also require clearance.

Local production: The technology has a compliant manufacturing process and is likely to have good volumes in the segment. However, it is not suitable for local production; end-to-end manufacture of this technology requires a high level of multidisciplinary expertise and specialized infrastructure. Some of the manufacturing know-how is likely to be with the contract or licensed manufacturers. In addition, given the intellectual property landscape of the product, the manufacturing know-how is likely to be closely guarded in the immediate future. The business model of the technology should also be considered.

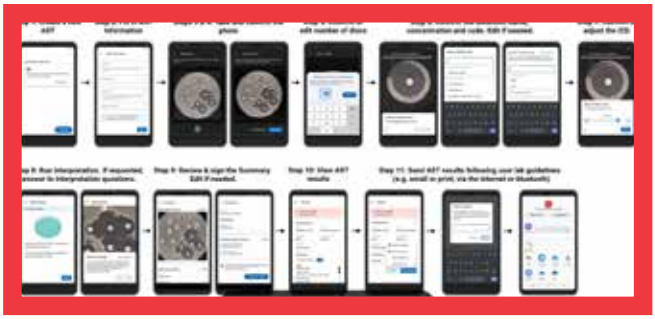
WHO guidance

- WHO recommendations for antenatal care for a positive pregnancy experience. (2016). https://iris.who.int/bitstream/handle/10665/250796/9789241549912-eng.pdf?sequence=1
- Manual of diagnostic ultrasound / 2nd ed. Vol 1 (2011). https://www.who.int/publications/i/item/9789241547451
- Manual of diagnostic ultrasound / 2nd ed Vol 2 (2013) https://www.who.int/publications/i/item/9789241548540

Newly commercialized technologies

Newly commercialized

Antimicrobial susceptibility testing interpretation*



Country of origin | France
Primary use | Diagnosis/measurement/ monitoring
Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 0
Year of commercialization: 2022
Number of units distributed: Not applicable
Currently marketed in: Central African Republic, Democratic Republic of the Congo, Jordan, Mali and Yemen
Model: 1.3 (certified with IVDD directive)

Product description

Antibiogo is a stand-alone software medical device application intended to support laboratory technicians in measuring inhibition zone diameters and interpreting antibiotic susceptibility tests (AST) from processed bacterial cultures from clinical samples. Antibiogo is intended to be used by trained laboratory technicians and non-experts in microbiology, operating in resource-limited LMIC.

Product details

Accessories: Not applicable
Consumables: Not applicable
Warranty duration: Not applicable
Lifetime: yearly following EUCAST & CLSI updates
Energy requirements: Not applicable
Facility requirements: Clinical bacteriology laboratories

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*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

Antimicrobial resistance (AMR) is a growing challenge worldwide. In low-resource settings, access to a limited number of antimicrobials increases the need for adequate susceptibility testing, as the development of resistance must be avoided.

This technology is software made available to the user as a smartphone application, intended to support laboratory staff in performing antimicrobial susceptibility testing (AST). It supports measurement of inhibition zone diameters on antibiograms and breakpoint result interpretation. Overall, this technology seems useful for performing AST in laboratory settings where professionals may not have specific microbiology training, particularly in resource-limited LMIC.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer has provided specifications for all software technical features and related documents. At the time of this report creation, WHO/UNICEF technical specifications were not available to compare this type of technology.

Regulatory

Pre-market assessment	Proceed
Post-market assessment	Proceed with caution
Quality system assessment	Proceed with caution
Security	Proceed with caution

Pre-market: Based on the certification and standards for performance, the documentation submitted was enough to demonstrate that the product is safe and effective.

Post-market: The manufacturer declared that they have some of the post-market documentation but did not submit the post-market surveillance and vigilance documentation. According to the submission, there have been no recalls or adverse events reported. Nevertheless, it is considered good regulatory practice to establish the complete PM system before introducing the product to the market.

Quality management system (QMS): The manufacturer does not have certified QMS ISO13485:2016, and based on the certification and standards for the performance, it cannot demonstrate that the product is safe and effective

Security: The manufacturer has declared conformity to IEC62304 software validation for the lifecycle of the device which mitigates cyber security risk but did not submit the validation report. The manufacturer has submitted risk management and risk analysis documentation. Introduction of this technology leads to cybersecurity risk, which is addressed through risk management.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	→	
Safety	!	
Economy	→	
Organizational	→	
Legal	→	
Social	→	
Ethical	→	
Green environment	N/A	

Antibiogo is a stand-alone software application for smartphones. It may enhance use of AST for patient treatment and surveillance, through capacity building of laboratory technicians to interpret the tests and supporting clinicians in making informed decisions regarding the selection of the most appropriate antibiotics.

This innovative technology may serve as a valuable tool, particularly in situations where the presence of microbiologists is limited by assisting laboratory technicians trained in its use, to read AST tests. Widespread adoption of Antibiogo contribute significantly to reducing the burden of AMR and promoting more rational use of antibiotics in LMICs. While it is currently limited to addressing 10 types of bacteria, it is considered a positive step towards better patient treatment of bacterial infections in low-resource settings. The manufacturer and innovator, Médecins Sans Frontières (MSF), has extensive experience in addressing health-care needs in LMICs worldwide. The proposed technology is well documented, and MSF provides it free of charge, with comprehensive training procedures and material for users.

Technology readiness level 9

Technology evidence assessment Recommended

Health technology management

- Durability: N/A
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The Antibiogo app is a semi-automatic method for AST measurement and interpretation when neither a clinical microbiologist nor automatic devices for interpreting AST are available. The technology requires an Android smartphone and Internet access to download and update the app, as well as for specific features such as sharing or remotely approving results. However, the AST measuring and interpreting function can be run offline, making it well-suited for a low-resource setting.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production: N/A

Intellectual property: This technology is protected by copyright (third-party modules are also used). Open access exclusively on the user side.

Local production: It is a ready-to-install software

WHO guidance

- Antimicrobial resistance https://www.who.int/health-topics/antimicrobial-resistance

Newly commercialized

Electroencephalography instrument/device*

Country of origin | Denmark
Primary use | Diagnosis/measurement/monitoring
Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 3500
Year of commercialization: 2023
Number of units distributed: 9
Currently marketed in: Kenya
Model: BC-1

Product description

BrainCapture's BC-1 technology is an affordable diagnostic solution that enables portable, hospital-grade electroencephalography (EEG) diagnoses without a neurologist or an EEG technician onsite. The BC-1 consists of:

(1) a low-cost device for capturing medical-grade EEG recordings, consisting of an amplifier and electrode cap (with 27 or 21 electrodes); (2) a proprietary smartphone application that can guide a non-expert to perform a medical-grade EEG test; and (3) a cloud-based telemedicine solution that allows secure transfer of patient data to be read by a remote expert and communication between experts and clinicians at the point of care.

Product details

Accessories: BC-1 Charger BC-1 Charging cable ECG electrodes instructions for use (IFU)27/21 pin cap adapter

Consumables: For easier, more comfortable recording, we recommend the following accessories and consumables: A syringe and needle to apply the conductive gel into the cap electrodes, a conductive gel to lower the resistance between the scalp and the cap electrodes. This improves measurement of brain signals. A measuring tape to find the proper cap size to fit the patient. Alcohol swabs to clean the wrists before putting on the ECG electrodes. A brush to clean the cap electrodes after use. A cap manikin for proper cap storage/display

Warranty duration: BrainCapture offers a 1-year warranty for the medical product BC-1. An extended warranty is available on request. A limited 6-month warranty is available for parts that have been replaced, which only applies to the scope of the replaced part. Support shall be given via email, telephone or Skype.

Lifetime: 3 years

Energy requirements: The BC-1 operates independently of the electrical grid once charged. It is equipped with a 3.7V 2000mAh lithium polymer battery, which enables the device to perform up to 30 recordings, each lasting 30 min, on a single battery charge. The following BC-1 charger specifications apply: Medical grade (2 x MOPP from input to output according to EN 60601-1:2006), Input (AC): 100–240 V, 50–60 Hz Output (DC): 5 V, 1.5 A The charger is a part of BC-1, and shall not be replaced by a different power source.

Facility requirements: Electrical power supply: To ensure compatibility and proper functioning of the BC-1, the facility should provide access to an electrical power supply within the range of 100–240 V and 50–60 Hz to support the BC-1 charger. Smartphone: A precondition for performing EEG recording is a smartphone with a BC-1 mobile application installed. The smartphone must have Android OS (10 or above) with at least 2GB of ram and 1600x720px resolution. Additionally, it requires free memory space (minimum 1 Gb) and Bluetooth 5.0 BLE with PHY2 capabilities. Internet Access: The BC-1 system requires access to the Internet for authentication, upload of data, access to EEG interpretation and patient administration. For upload of data, a stable minimum 500 Kb/s connection is recommended (either WiFi, or mobile data).Proximity between the BC-1 amplifier and smartphone: Since the BC-1 amplifier transmits signals to the user's smartphone app via Bluetooth (BLE 5.0), the maximum acceptable range between the amplifier and smartphone shall not exceed 30 m. Additionally, consideration should be given to any physical obstacles or other electronic devices that may interfere with BLE 5.0 connection. Environmental conditions: The BC-1 can be stored and operated optimally in indoor environments with temperatures of 10–40°C, humidity 15–95% and altitudes -500–3000 m above sea level.

Contact: Tue Lehn-Schiøler | Phone: +45 3051 9721 | Web: https://bit.ly/3XQv2if

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical — Recommend with caution

Epilepsy is a chronic neurological condition that requires prompt diagnosis and treatment to prevent significant morbidity. The cornerstone of epilepsy diagnosis and management is the EEG. Traditional EEG machines are cumbersome and sensitive devices, requiring highly skilled technicians for their operation. These constraints, coupled with the absence of qualified electrophysiologists for interpretation, means patients in rural and low-resource settings are often left undiagnosed and untreated.

This technology is a battery-operated and portable medical device composed of a recording tool that is connected to an electrode head cap. The device can be connected by Bluetooth to a smartphone, which allows upload of examinations to the cloud and subsequent remote evaluation by a physician. The app also provides an AI-based EEG interpretation software. Due to its ease of use, this device may significantly extend access to EEG examinations to currently underserved populations. However, the automated interpretation software's performance needs improvement, as agreement between the app and human interpretation is still significant, especially focalized epileptic activity.

Regulatory

Pre-market assessment	Proceed
Post-market assessment	Proceed with caution
Quality system assessment	Proceed
Security	Proceed with caution

Pre-market: This product has obtained market approval in Kenya. The manufacturer has submitted the design verification and validation test reports and shared the list of standards to which the product conforms. On the basis of the certification and standards for the performance, the documentation submitted is adequate to demonstrate the product is safe and effective.

Post-market: The manufacturer did not submit complete post-market surveillance and vigilance documentation to monitor the safety and effectiveness of the product after placement in the market.

Quality management system (QMS): Based on the certification and standards, the manufacture of the product conforms to ISO13485:2016, the product is safe, and performance is in accordance to the intended use.

Security: The manufacturer did not submit complete risk management documentation based on ISO14971:2019. The introduction of this technology leads to cybersecurity risk; software validation based on IEC62304 and risk management based on ISO14971 would have addressed these issues and mitigated this risk.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	Proceed	
Safety	Proceed	
Economy	Proceed with caution	
Organizational	Proceed with caution	
Legal	Proceed	
Social	Proceed with caution	
Ethical	Proceed with caution	
Green environment	Proceed with caution	

The BC-1 solution boasts various advantages including affordability that results in increased accessibility. As stated by the innovator, the technology has obtained market authorization from the Kenya Pharmacy and Poisons Board, with a pending CE mark approval. Innovation costs 3500 USD, in contrast to standard EEG equipment from leading vendors, which typically cost 200 000–350 000 USD Furthermore, its use does not require organizational changes or the adoption of additional legislation. As highlighted by the innovator, the BC-1 is environmentally friendly and sustainable due to its lower energy consumption and extended product lifespan; however, the only evidence provided was the innovator's claims.

Technology readiness level 9

Technology evidence assessment Recommend with caution

** This assessment was initiated November 2023

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer has provided the necessary, well-detailed technical specifications mainly through the supporting technical documentation provided (i.e. instruction and user manual). At the time of this report creation, WHO technical specifications were not available to compare this type of technology.

Health technology management

Durability

Ease of Use

Ease of maintenance

Environmental conditions

Affordability

Local access to technical support

Ease of cleaning

Infrastructure requirements

Health-care delivery platform

The Braincapture is a portable, battery-operated, and water-resistant device with a mobile app-based EEG acquisition device. It has a head cap containing electrodes prepositioned in standard EEG acquisition locations allowing untrained personnel to conduct examinations. The user must provide an Android smartphone for the acquisition app. A potential drawback is that interpretation of results may require Internet connectivity. Although AI is used for the interpretation of results, no study has been conducted to confirm the accuracy of the interpretation. However, results can be interpreted by human neurologists using the same software platform.

One advantage of the device is that it does not require preventive maintenance. However, it may require corrective maintenance, such as a battery replacement, which can only be performed by the manufacturer. Shipping the device back may pose a problem due to the high transportation costs associated with such returns. Even though spare parts are supplied by the manufacturer, they must be transported directly from the factory. Currently, local support is provided only in Kenya. The manufacturer states in the submitted report that physical, chemical, and biological safety testing has been conducted. The durability of the device cannot be fully verified since only one certificate indicates that testing has been performed.

Intellectual property and local production

Technology transferability

Open source/ access

Local production

Intellectual property: This technology is protected by copyright and patents. The device uses proprietary software, and patents are pending. The use of all intellectual property will require clearance.

Local production: The technology has a compliant manufacturing process. However, the device is in an early phase of commercialization and hence might evolve further. The technology has a weak business case for end-to-end manufacture as the technology is highly import dependent, requires a comparatively high level of technical and quality control expertise, availability of a robust, consistent, and highly flexible supply chain in the region and related in-house manufacturing infrastructure.

WHO guidance

- Improving the lives of people with epilepsy: a technical brief. (2022). https://iris.who.int/bitstream/handle/10665/365270/9789240064072-eng.pdf?sequence=1

Newly commercialized

Passive, contact-free, continuous vital sign monitoring*

Country of origin | Republic of Korea

Primary use | Diagnosis/measurement/monitoring

Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 285

Year of commercialization: 2021

Number of units distributed: 7800

Currently marketed in: Australia, Republic of Korea, Singapore, USA

Model: XK300

Product description

Xandar Kardian's XK300 utilizes UWB radars to automatically obtain resting heart rate, resting respiratory rate, body motion index and presence (in bed/room) detection. Since it uses radar, it is 100% contact-free and collects vital signs continuously. On average, the sensors pick up 6000 or more data per patient, every 24 h. It is being deployed in the USA at various skilled nursing facilities, which has resulted in an average of 2 days early detection of health deterioration - before the onset of symptoms of COVID-19, heart attacks, sepsis, and even urinary tract infection without the need for any staff to monitor or relying on patient compliance.

Product details

Accessories: Gateway is required if the health data are to be sent to a cloud based dashboard connected to an EMR system. The system is designed to run on-premise so that no Internet connection is necessary to use the device. Data transmission is optimized, so multiple devices can use a single LTE gateway to stream data continuously to remote clinicians.

Consumables: This is a non-contact, ambient, passive monitoring device. Therefore, it does not have any consumables and is designed to run for more than 10 years in the field.

Warranty duration: 2 years full warranty + 3 years conditional (based on application and field environment).

Lifetime: 10 years

Energy requirements: 700 mW power ~ less than 1W. It is not designed for battery power, but can run 10 days with a 20 000 mAh battery pack.

Facility requirements: AC/DC power source. It can work on power over ethernet or even solar power that charges the battery which can sustain continuous 700 mW of power usage when turned on. Wi-Fi is preferred, but it can run on Lorawan, narrow band Internet of Things, Long-term Evolution or even on-premise (no connection). XK300 has been field tested in various countries and facility environments.

Contact: Sam Yang | Phone: + 41 633 38170 | Web: https://bit.ly/4cNF4Fd

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical — Recommended with caution

Vital signs remain at the centre of the monitoring of any patient, in health or disease states, in all settings. Equally, detection of early deterioration is essential during patient monitoring, to ensure timely reassessment and transfer. Traditional vital sign monitoring can involve multiple contacts between a patient and health-care providers, which can be problematic during an infectious disease outbreak. Likewise, adequate cleaning and disinfection of equipment between two patients can sometimes be problematic, so contactless remote monitoring systems can be advantageous in this context.

This solution provides a contactless remote monitoring system for heart and respiratory rate, with preclinical and clinical use in neonates and adults, with promising results. Blood pressure and body temperature would require separate assessment. As the device is designed to monitor only one patient, its use may be limited in settings when adequate patient distancing cannot be assured.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer does not provide the user manual (just an installation manual). Moreover, the specifications described in the submission form are missing many important details such as the respiratory rate and the resting heart rate measurement ranges and their related accuracies. At the time of this report creation, WHO/UNICEF technical specifications were not available to compare this type of technology with a radar-based technology that measures only "resting" vital signs (respiratory rate and resting heart rate) and body motion/detection, as no vital signs monitoring system/unit technical specification documentations were available at WHO/UNICEF.

Regulatory

Pre-market assessment	Proceed
Post-market assessment	Proceed with caution
Quality system assessment	Proceed with caution
Security	Not acceptable

Pre-market: This product is a class II medical device in the USA and class IIa in the EU and Australia and has obtained market approval in Australia, the Republic of Korea, Singapore, and the USA.

Reports were not submitted to demonstrate compliance with the relevant standards.

Post-market: The manufacturer did not submit the post-market surveillance and vigilance documentation. The complaint handling, recall, and adverse event reporting documents were not declared.

Quality management system (QMS): The manufacturer did not submit documents on ISO13485:2016 or e-QMS USFDA standard to demonstrate that manufacture of the product conforms to these standards and hence it is not possible to verify.

Security: Security assessment was not declared and therefore could not be verified.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	Proceed	
Safety	Proceed	
Economy	Proceed with caution	
Organizational	Proceed with caution	
Legal	Proceed	
Social	Proceed	
Ethical	Proceed	
Green environment	Proceed	

Adoption of this radar sensor technology in low-resource settings (LRS) could represent a step forward in health-care services, tailored to the unique challenges of those regions. With its cost-effective pricing model, particularly the one-time cost option in LRS, this technology is an accessible solution for advanced patient monitoring. Its effectiveness in non-invasively tracking of multiple patients' vital signs simultaneously while reducing the burden of continuously checking all patients could facilitate health-care delivery, potentially leading to improved health outcomes through early detection and intervention. The installation procedure should be considered prior to adoption. The ease of use by end users further enhances its appeal, ensuring that health-care facilities with limited technical resources can adopt it without substantial infrastructural or personnel changes. Moreover, the technology's environmental benefits, such as reduced energy consumption and waste, align with the growing need for sustainable health-care solutions. Ethically, it upholds patient dignity and privacy while offering equitable access to state-of-the-art health-care monitoring.

Technology readiness level 9

Technology evidence assessment Recommended

Health technology management

- Durability: N/A
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The product provides distant monitoring of vital signs through radars in rooms. Patients who are not restricted to a bed can move around while being monitored. The durability will need testing in harsh conditions. No testing has been done so far and no data have been collected in hot, humid, dusty, and above all non-climatized environments. The technology does not require preventive maintenance, resists high and low temperatures, and can technically function with solar-powered battery packs. The affordability depends on the number of spaces and people the system is monitoring. It is not clear whether one system can identify and simultaneously monitor several patients. It is therefore less affordable than centralized care but offers a different, more preventive service. Recurrent subscription is a risk in public health settings in low-resource settings. The usability is not clear (platform or app to read data, who is in charge, how are alarms sent to health workers, will they move to see the patient, will the patient go to the health facility), nor is it maintenance. The product is not primarily developed for low-resource settings, and adapted information and evidence will be necessary to assess it use in such settings.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: The software is proprietary. Some of the critical technologies in the device are third-party dependent. The software is under trade secret and copyright protection. Evidence of a registered trademark is not available for the product. This technology is copyright and patent-protected, the use of all intellectual property will require clearance. Some of the patents are pending.

Local production: There is a weak business case for local production. Manufacturing know-how is with contract manufacturers. Highly import dependent, and requires high-level technical expertise and technology infrastructure.

Prototypes technologies

Prototype

Automated multiplex diagnostics system*

Country of origin | China

Primary use | Diagnosis/measurement/monitoring

Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 32 000

Expected year of commercialization: 2023

Number of existing prototypes in use/trials/tests: 10

Currently used in: China

Model: MPA-G01R06

Product description

The system fully automates conventional laboratory-based PCR processes in an all-in-one system with three elements: an analytical machine, a microfluidic reagent cartridge, and software. Pre-handling is minimal as it automatically runs extraction, reagent dispensing, nucleic acid amplification, signal detection, and analysis. The design is a combination of engineering, biochemistry, and production know-how, delivering a high-quality diagnostic system at an affordable cost. Innovative amplification methods and proprietary primer design enable simultaneous 42-plex multiplex detection while maintaining superior sensitivity and specificity.

Product details

Accessories: Control PC, barcode scanner (optional), keyboard and mouse set (optional)

Consumables: Reagent cartridge

Warranty duration: One year warranty and thereafter maintenance and service package available

Lifetime: 8 years

Energy requirements: 200-240V, 50/60 Hz, 700 W (maximum), 10A fuse; 100V or other values are available depending on the targeted countries/regions

Facility requirements: Operating temperature of ~18-28 °C; Operating humidity between 10 and 90% RH; maximum altitude of 2000 meters. Suitable for point-of-care settings.

Contact: Prof. Terence Lau; Ms Bianca Ko | Phone: (852) 2389 6899 | Web: https://bit.ly/45Ryo6l

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical — Recommended with caution

The technology is a system composed of an automated multiplex analyser (instrument) machine, a microfluid reagent cartridge with a panel of assays and interpretive software. The manipulation steps are few, given the design of the instrument and cartridge. The current test cartridge targets 42 respiratory pathogens (28 viruses, 11 bacteria and 3 fungi). This is a fully automated point-of-care diagnostics system. It can provide results in less than 1.5 h without a resource-intensive laboratory, multiple equipment, or trained technicians. As it is a point-of-care system, it performs the test one sample at a time.

Overall, this technology would add value by allowing a comprehensive and relatively fast diagnosis of the targeted panel of respiratory pathogens with a very high level of performance.

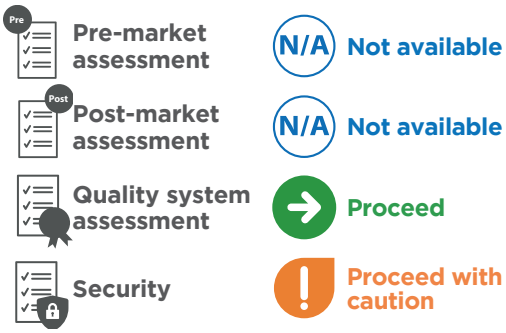
** This assessment was initiated November 2023

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer provides detailed technical specifications, and their declarations are well supported by technical documentation (that is, instructions and a user manual). At the time of this report's creation, WHO technical specifications related to an automated PCR analyser were not available to compare the proposed technology.

Regulatory



Pre-market: The manufacturer has shared the design verification and validation test reports. The submitted documentation does not adequately demonstrate the clinical sensitivity and specificity of the product, or its clinical performance. The manufacturer has not conducted a clinical evaluation of the product yet.

Post-market: The manufacturer has briefly described customer complaints and field safety corrective action procedures.

Quality management system (QMS): The manufacturer has submitted a ISO13485:2016 which is valid until 8 June 2025. Based on the certification and standards, the manufacturing of the product conforms to ISO13485:2016. The product is safe and effective, and its performance is in accordance with the intended use.

Security: This technology could introduce a risk for biosecurity.

The manufacturer must submit complete risk management documentation based on ISO14971:2019, the risk analysis, risk management plan, risk control, post-production information, and other hazard reports.

The manufacturer must declare conformance to IEC62304 software validation for the lifecycle of the device and to address the cybersecurity risk.

Health technology assessment

The innovator has published a study that suggests that the system offers superior performance for bacteria identification, while the overall performance is comparable to standard single-tube single-target PCR. The system is better in terms of costs, turnaround time, and higher multiplexing than the standard of care.

The technology is safe, and risk procedures have been set according to ISO 13485; however, there is no clear information on any risk assessment performed. Only basic training appears to be required. User and instruction manuals have been included. There is no specific evidence on legal aspects, but, in principle, the technology should not require additional legislation. While there is no evidence on social aspects, the innovator states that the Innovation and Technology Commission of the Hong Kong SAR (China) Government, users at the Queen Mary Hospital and the Queen Elizabeth Hospital, and frontline clinics in Hong Kong and Macau SAR (China) provided substantial support. There is no substantiating evidence regarding any aspect of the green environment. According to the innovator, the system reduces carbon emissions by eliminating the need for transport to a laboratory and minimizing reagent use and energy consumption. The cartridges are disposed of as clinical waste per EU laws on waste from electrical and electronic equipment. The system is reusable, but recyclability is limited due to the nature of medical diagnostic end products.

As confirmed by further evidence, the product is innovative in terms of multiplexing functionalities, large sample intake, better sample volume extraction and cleaning, and lower costs.

Technology readiness level 8

Technology evidence assessment Recommend with caution

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The Avalon Automated Multiplex System is an IVD device that uses a reagent-prefilled cartridge system, intended for running multiplex PCR. After the sample has been inserted into the cartridge, it is placed in the system tray for measurement. The result is printed after the screening of multiple respiratory target pathogens. The sample can be discarded after its use as biological material. In the future, the platform offers the possibility of adding more tests. A refrigerator is necessary, as part of the infrastructure requires storing the cartridge at 2-8°C when not in use. Integrated into one single unit, this device substitutes for the usual laboratory devices required for PCR tests. Its limitation to testing one sample at a time, taking 1.5 h for testing, and use of manufacturer-supplied consumables may prove to be an inconvenience in some situations. The evaluation of durability in low-resource settings is not feasible due to the absence of supporting evidence. The fact that replacement parts are currently available only in China may make it more difficult for people in other countries to access local support.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: This technology is protected by copyrights, trade secrets, and patents. The software is proprietary. The use of all intellectual property will require clearance. Caution is advised due to pending patent applications and the likely dependence on third-party intellectual property for manufacturing critical parts.

Local production: The technology has a compliant manufacturing process; however, the device is in the early phase of commercialization and hence might evolve further. The technology has a weak business case for end-to-end manufacturing, as it is highly import-dependent and needs a comparatively high level of technical and quality control expertise, the availability of a robust, consistent, highly flexible supply chain in the region, and related in-house manufacturing infrastructure.

Prototype

Digital microscope*

Country of origin | United Republic of Tanzania
Primary use | Diagnosis/measurement/monitoring
Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 600

Expected year of commercialization: 2025

Number of existing prototypes in use/trials/tests: 100

Currently used in: Cameroon, Rwanda, United Kingdom, United Republic of Tanzania and USA

Model: OpenFlexure Microscope v7

Product description

The OpenFlexure Microscope is a fully motorized digital microscope capable of scanning and tiling samples automatically. It has primarily been developed for use with 100x oil immersion objective lenses for malaria diagnostics. However, it can also be configured for a wide variety of other conditions, including other parasitic diseases and oncology.

Product details

Accessories: Standard ancillary equipment is required for staining and preparing samples. Computers are required for the operation and read-out of scanned samples.

Consumables: Lubrication oil, lead screws (replacement annually), reagents for staining (Giemsa stain, distilled water, microscope slides, etc.), immersion oil if required.

Warranty duration: 1 year (dependent on manufacturer: this design will be available from a range of manufacturers).

Lifetime: 5 years (if maintained correctly).

Energy requirements: Intermittent electrical power (can run for ~1 day on battery power from a standard 20Ah 5V battery pack).

Facility requirements: For standard optical microscopy: requires a laboratory bench, sink, drying facilities, and reagents for sample preparation.

Contact: Richard Bowman | Phone: +44 7751627671 | Web: https://bit.ly/3xA9nk1

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

The technology is a digital microscope that uses a digital sensor instead of eyepieces. It is equipped with three motors to translate the sample and focus the microscope. It is accompanied by software capable of automatically focusing and acquiring images over a wide region of the sample and stitching the images acquired into a single digital representation of the slide. It has primarily been developed for use with 100x oil immersion objective lenses for malaria diagnostics. However, it can also be configured for a wide variety of other conditions, such as other parasitic diseases and oncology.

Overall, this technology is very useful as it makes it more accessible to low-resource settings that currently have only manual microscopes, enhancing technician training, record-keeping, and quality assurance.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

WHO has a technical specifications document available, dated 2014 (last modification), referring to a basic binocular microscope. This WHO technical document would not be fully appropriate the specifications of the technology proposed since the manufacturer does not provide any supporting and/or technical documentation, such as a user manual. It has not been possible to verify what was claimed in the submission form or retrieve the missing technical information.

The main requirements that cannot be verified are the following: objectives shall be held on a rotating changer with a ribbed grip for easy rotation and click stops, accommodating at least three at once; eyepiece interpupillary distance adjustable with a minimum range of 54–74 mm; the sub-stage condenser shall be fitted with an aspherical lens and an iris diaphragm; the slide holder shall have spring-loaded side clamps; the slide stage shall have a Vernier gauge rule in at least one dimension, with movement possible in both X and Y directions with a range not smaller than 60 mm for the x-direction and 40 mm for the y-direction; wide-field eyepieces at least 10x and 15x; at least the following plan achromatic objectives are provided: 4x, 10x, 40x, and 100x (oil immersion) with numerical aperture; anti-fungus-treated observation tubes, eyepieces, and objectives.

Regulatory

Pre-market assessment	N/A Not available
Post-market assessment	N/A Not available
Quality system assessment	N/A Not available
Security	N/A Not available

Pre-market: The product is in the early prototype stage and needs to undergo preclinical testing and clinical evaluations before regulatory approval. The premarket documentation is not complete.

Post-market: The manufacturer did not submit surveillance and vigilance documentation to monitor the safety and effectiveness of the product after placement in the market.

Quality management system (QMS): The manufacturer site is not certified to the ISO13485:2016 quality management system and is unable to demonstrate that the product is safe and effective.

Security: The manufacturer did not submit risk management documentation, risk analysis, risk management plan, risk control, post-production information, or other hazard reports.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	→	
Safety	!	
Economy	!	
Organizational	→	
Legal	!	
Social	!	
Ethical	!	
Green environment	→	

The OpenFlexure Microscope shows its potential in resource-limited health-care settings. Supported by evidence demonstrating affordability, customization, and accessibility, it offers remote diagnosis and digital archiving, presenting significant advantages over the standard of care. The ability of the company to manufacture medical devices on-site or locally through 3D printing can reduce the need for long-distance transport of products, thereby lowering the carbon footprint associated with shipping. Error detection mechanisms render safety concerns comparatively insignificant. Although a detailed budget impact analysis was absent, the economic feasibility seemed promising. Although organizational changes may be required, the documentation was insufficient. Caution is advised when making recommendations regarding legal, social, ethical, and environmental factors due to the scarcity of corresponding information. Further assessment of safety, ethical, and social aspects is crucial for a comprehensive evaluation and endorsement.

Technology readiness level 6

Technology evidence assessment Recommended

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The digital microscope is an open-source project in which the aim is to provide several manufacturers with designs to locally produce devices in LMICs. This device is used in conjunction with software to control and obtain the images that are also part of the project, but it is installed on a computer supplied by the end user. It is based on a conventional bright-field optical microscope with the improvement of motorized adjustments and image sensors but maintaining standard parts such as the 100X oil immersion objective or LED light source.

The digital microscope is unique because mechanical parts are 3D printed; this allows resolution of supply chain issues. The rated duration is 5 years if correctly maintained. The advantage is that the open source project allows production of the microscopes in the same countries in which they are used, facilitating procurement of the devices, technical support, and availability of parts. The cost will be similar to that of microscopes imported from manufacturers in other countries, owing to the documentation capabilities of its software and the advantage of receiving local technical support.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production (N/A)

Intellectual property: Open-Source Technology. Technical details for commercialization or further development of the technology are available in the public domain. The use of patented, compatible third-party products may require clearance.

Local production: No evidence was provided of a systematic product development approach. It is in an early prototype phase and it is not ready for local production.

WHO guidance

- Malaria Microscopy Quality Assurance Manual – Version 2. (2016). https://www.who.int/docs/default-source/documents/publications/gmp/malaria-microscopy-quality-assurance-manual.pdf
- Basic Malaria Microscopy – 2nd edition. (2010). https://iris.who.int/bitstream/handle/10665/44208/9789241547826_eng.pdf?sequence=1

Prototype

Laptop cystoscope*

Country of origin | India
Primary use | Treatment/resuscitation/palliative care/surgery
Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 1000
Expected year of commercialization: 2024
Number of existing prototypes in use/trials/tests: 15
Currently used in: India, Kenya, Nigeria and Uganda

Product description

The Laptop Cystoscope is a device that functions similarly to the conventional cystoscope used for diagnosis and minor procedures available at a small fraction of the cost of the conventional cystoscope and does not require common accessories such as a light source, camera or monitor which are required for the conventional cystoscope. It can be connected to a laptop computer or cell phone and derives power from the computer/cell phone.

Product details

Accessories: The complete set includes the commercially available outer sheath of the cystoscope and accessories like the graspers, bugbee electrode and the bottle for bladder wash.

Consumables: None for diagnosis. DJ stents and guide wires are needed for minor procedures like DJ stenting and bugbee electrode for vaporization of lesions

Warranty duration: One year

Lifetime: 5 to 10 years

Energy requirements: Minimal from a Laptop computer

Facility requirements: None other than privacy and for lithotomy position. Has been used for life -saving DJ stenting on both sides in remote areas with no power supply.

Contact: Gnanaraj Jesudian | Phone: +91 9442543377 and +91 8056310595 | Web: https://bit.ly/3XPGt9Y

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical — Recommended with caution

Lower urinary tract disorders require cystoscopy for adequate workup and management. Rigid cystoscopes allow physicians to perform biopsies, cauterize lesions, or perform ureteral stenting. Conventional rigid cystoscopes require large and sensitive equipment, making their deployment in low-resource, remote settings difficult.

This technology builds on the design of conventional cystoscopes by simplifying the device's optics and allowing connection to a laptop. The video feed can be transmitted remotely, allowing for remote training and proctoring. This can expand access to cystoscopy to patients in remote areas. However, some infrastructure is required to perform rigid cystoscopy, as it requires some degree of sedation and analgesia. Urethral damage, bladder rupture, and haemorrhage are known complications and may require surgery.

Despite extending access to this procedure, it must be performed in the correct setting.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer provides technical information on the submission form. Additional supporting documents, such as the instruction manual, have been provided but they do not include the essential chapters, sections, and technical information that should be specified in a technical document of this nature. At the time of this report creation, WHO technical specifications were not available to compare this type of technology.

Regulatory

Pre-market assessment	N/A Not available	**Pre-market:** This prototype product is a Class IIa medical device in the EU. The premarket documentation is not complete.
Post-market assessment	N/A Not available	**Post-market:** The manufacturer did not submit the surveillance and vigilance documentation as well as risk management documentation (such ISO 14971).
Quality system assessment	N/A Not available	**Quality management system (QMS):** This manufacturing site is not certified to ISO13485:2016 quality management system. Based on the certification and standards, no documents were available to demonstrate the product is safe and effective.
Security	N/A Not available	**Security:** The introduction of this technology leads to cybersecurity risk and no evidence of the management of this risk is provided by the manufacturer.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	!	
Safety	!	
Economy	!	
Organizational	→	💡
Legal	→	
Social	→	💡
Ethical	→	
Green environment	→	💡

The Laptop Cystoscope is similar or equal to a commercially available rigid or flexible laptop cystoscope. The innovativeness of this product consists of a mix of existing technologies and processes of telemedicine educative initiatives to train local non-specialist surgeons to perform urological interventions. This long-studied technology (first study published in April 2011) made it possible to respond to patients' conditions and urgent needs when the COVID-19 pandemic lockdown was imposed. Local providers to explant or implant a vesical stent which resulted in removal of more than half of the patients' urological stones. The health and social benefits are important for this prevalent condition. Surveys show that about 5% of outpatients in rural India have urological problems, and less than 2% of these patients have access to urologists. The authors claim that more than two-thirds of patients with lower urinary tract symptoms could be diagnosed and treated with just a cystoscope. These local interventions can spare waiting times patients' suffering and deterioration and prevent sequels with remote surgery supervision. This welcomed initiative can be one relevant example of improving the sustainability of the health-care system, contributing to achievement of the Sustainable Development Goals.

Technology readiness level 6

Technology evidence assessment Recommend with caution

Health technology management

Health-care delivery platform

The laptop cystoscope is a camera with an integrated light source in a cystoscope handle. It is made of surgical-grade stainless steel and is submergible, which ensures durability. The resolution is high definition. The light source is at the tip, which may pose a problem of durability, as since the tip can heat up. This may also compromise repair, as the device must be waterproof and special tools are required to repair and achieve this. It requires a user-supplied laptop, android phone, or tablet, which cannot be evaluated for durability but opens up for flexibility. The instructions for setup, cleaning, and disinfection should be more detailed. Sterilization can be done with common disinfectants such as glutaraldehyde. No preventive maintenance is required, and corrective maintenance can be performed by a trained general technician.

Intellectual property and local production

Intellectual property: The innovator claims that there are no licensing agreements related to the technology and that third-party-owned intellectual property rights are not necessary for the production and sale of the technology. However, no information is provided about the legal relation between the innovator (claimed to hold intellectual property rights for the production and sale), the inventor (claimed to own the intellectual property rights), and Karunya University (the applicant for the patent).

When the patent is granted and if not made open source, as claimed, the technology will be patent protected. To use this technology, authorization from the patent owner or the assignee will be required.

Local production: This is a potential product for local production, but first, the manufacturer must ensure that the local production plants are certified to comply with all the regulations. The low appropriateness evaluation is based on the consideration that the existing manufacturing process includes importation of the components and assembly at the manufacturing site. The documentation indicates that there are extremely specific items such as CCD cameras, LED lamps, image processing boards, stainless steel tubes for the insertion section, that are unlikely to be manufactured in LMIC The device is used in conjunction with an outer sheath and bridge and, according to the company, those must be imported from other manufacturers. The company claims that its product is fully compatible with several brands of the above-mentioned items, without further information, thus providing flexibility for the production and use of the device, as, if some brand components become scarce, they can be substituted. This product is still in the prototype stage and should receive a few but very important updates regarding water tightness of the devices, their connectors, and cables. This should be done before the trials start; however, it should be ready soon for local production.

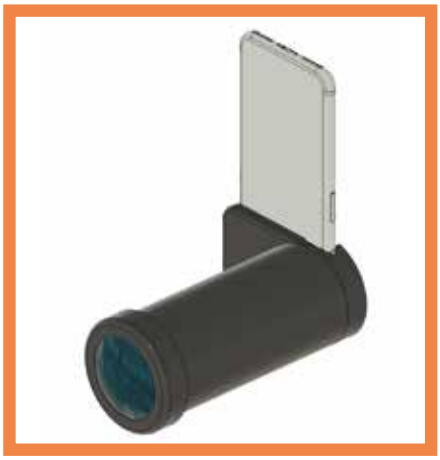
Prototype

Smart eye camera fundas model*

Country of origin | Japan

Primary use | Diagnosis/measurement/monitoring

Category | Medical device (including in vitro diagnostics)



Commercial information

List price (USD): 5000

Expected year of commercialization: 2024

Number of existing prototypes in use/trials/tests: 15

Currently used in: Tested for trials in Indonesia, Japan, Mozambique

Model: Software Version (as of 31 Oct 2023)

Product description

Smartphone attachment medical device which utilizes the camera and light source of the smartphone to observe the posterior segment without mydriation. The price is 5~10 USD per patient for single use. The detailed price will be set with the existing cognitive assessment and the national health insurance reimbursement policy in individual countries.

Product details

Accessories: The device is applicable to iPhone 7/8/SE2/SE3. The device is delivered with the applicable phones with the software (SEC App) installed and the charger of the iPhone as well as the hard-case for the device.

Consumables: Not applicable

Warranty duration: 2 years

Lifetime: 5 years

Energy requirements: Not necessary

Facility requirements: Please store in the attached case at the stable place. Carry by putting it in the attached case. Store under the following environment - Temperature: 4-35°C; Humidity, 30–80% (no condensation of moisture); Atmospheric pressure: 800–1060 hPa; Avoid direct sunlight, store away from any liquid. Store at the place away from flammable fumes/liquid.

Contact: Shintaro Nakayama, COO OUI Inc. | Phone: +81 80 301 48440 | Web: https://bit.ly/4eU9MP1

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical — Recommended with caution

Preventable blindness is one of the major public health challenges faced today. In low-resource settings, access to adequate ophthalmic care is hindered by the low availability of adequate equipment and trained professionals, delaying diagnosis and referral. Fundoscopy is an essential part of ophthalmic examination. However, use of an ophthalmoscope requires use of mydriatic drugs, as well as extensive training. Moreover, most ophthalmoscopes cannot acquire images (photography or video).

This technology simplifies several aspects of the fundoscopic examination. It is a compact device that transforms a smartphone into a device capable of performing a comprehensive examination of the posterior structures of the eye, without the need for mydriatic drugs. Through the smartphone's capabilities, it is also possible to record and transmit videos to other health-care professionals at different locations.

The device is currently undergoing several trials, with good preliminary results.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

This medical device is an ophthalmic camera that can be used on mobile phones to diagnose specific ophthalmic clinical issues. Similar medical equipment to compare technical requirements is a slit lamp which is not detailed in any technical requirements document in WHO or the UNICEF catalogue. Consequently, at the time of this report creation, WHO and/or UNICEF technical specifications were not available to compare this type of technology.

Regulatory

Pre-market assessment	N/A Not available	**Pre-market:** This is a prototype, therefore, the premarket documentation is not complete.
Post-market assessment	N/A Not available	**Post-market:** The manufacturer did not submit post-market surveillance and vigilance documentation.
Quality system assessment	Proceed with caution	**Quality management system (QMS):** Based on the certification and standards, the manufacture of the product conforms to ISO13485:2016.
Security	Proceed with caution	**Security:** The introduction of this technology does not lead to biosecurity or cybersecurity risk. The manufacturer did not submit risk management documentation, risk analysis, risk management plan, risk control, post-production information, or other hazard reports.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	→	
Safety	→	
Economy	!	
Organizational	−	
Legal	−	
Social	!	
Ethical	−	
Green environment	!	

The technology (Smart Eye Camera) is non-invasive and uses the light source and the camera of a smartphone to deliver ophthalmic diagnosis, while not introducing any additional safety risk. The technology is very safe especially since it does not require any external power supply. The associated risks are low, acceptable, and highly predictable. The expected clinical benefits are very high since it will enable non-ophthalmologists, nurses, and other health-care workers with no specific experience in ophthalmology to take good-quality ophthalmic images that can satisfy professional ophthalmologists, only after a short (<10 minutes) tutorial session. It is expected to play a critical role in improving the standard quality of ophthalmic services. The device is 80-90% less expensive than a conventional slit-lamp microscope (5000-8000 USD) and can extend the reach of accessible eyecare tremendously. The technology will allow delivery of eyecare to millions of patients (22 million blind and 1.1 billion visually impaired). It would broaden the possibility and capacity of local health-care workers in the rural areas and would save economic loss due to preventable blindness and visual impairment of the population greatly.

Technology readiness level 9

Technology evidence assessment Recommended

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The Smart Eye Camera Fundas model is designed as an alternative to the traditional portable fundas. The device consists of an app that is pre-installed on an iPhone with an included lens attachment that enables ophthalmological examinations in low-resource settings. The app is easy to use by health-care workers, including non-ophthalmologists. It promises to be more cost-effective than the current standard of care due to the lower cost of the device and the possibility of task shifting to any health-care worker.

Maintenance of the lens attachment is minimal, but the durability of the phone is dependent on careful handling according to the manufacturer's instructions. Currently, the app and attachment are only compatible with iPhones, which generally are more expensive to repair in LMICs.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: This technology is protected by copyrights, patents, and registered trademarks. Some patents are pending, and trade secrets are likely to exist. The use of all intellectual property will require clearance.

Local production: Only the SEC Fundas model is considered (the mobile phone is excluded from the scope of evaluation for local production).

Currently, the product is in the prototype/clinical trial phase, hence cannot be considered for local production . The product is likely to evolve further.

Updates of commercially available technologies

Field oxygen rebreathing system*

Country of origin | Sweden
Primary use | Other
Category | Medical device (including in vitro diagnostics)

Year published in compendium: 2021

Commercial information

List price (USD): 2 870
Year of commercialization: 2020
Number of units distributed: 100-150
Currently marketed in: Democratic Republic of the Congo, France, Iceland, Israel, Spain, Sweden, United Kingdom
Model: FIDO

Product description

FIDO is a portable breathing apparatus that distributes oxygen. FIDO has the same technology as a diving rebreather, which absorbs the carbon dioxide from the exhaled breath to permit recycling of the unused oxygen. Extra oxygen is added to replace the amount metabolized by the user under treatment. The design of FIDO is compact, small, and lightweight, enabling it to be carried to the scene of the incident. The patented oxygen-air mixing valve provides an action time of around 1 h.

Product details

Accessories: FIDO is used with standard mask and bio filter similar to that used with the current system.
Consumables: FIDO is used with oxygen and also cartridges that collect the CO_2.
Warranty duration: 5 years
Lifetime: 5 years
Energy requirements: FIDO is 100% mechanical, requiring neither electricity or a battery
Facility requirements: None

Contact: Christophe Galan | Phone: +44 79 691 00942 | Web: https://bit.ly/4cPTlBc

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Proceed

Oxygen therapy is a cornerstone of medical care. Many conditions can cause type I respiratory failure, and supplemental oxygen is critical to patient outcomes. However, oxygen is not readily available in many parts of the world, especially in LMIC.

Type I respiratory failure causes hypoxaemia which can lead to patient death if not adequately managed. Supplemental oxygen is the only way to correct it. Conventional oxygen therapy can waste oxygen, as only a small fraction of it is extracted by the lungs. Carbon dioxide levels, however, rise about tenfold. This device allows for an extremely efficient use of supplemental oxygen, as the exhaled air is enriched and rebreathed. A chemical scrubber removes excess carbon dioxide, ensuring narcosis does not ensue. Oxygen use is reduced, and a more efficient use of oxygen is attained. Several safety features are built into this, making it an excellent solution for oxygen therapy in all settings.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer provides the necessary technical specifications supporting and detailing their declarations with appropriate and complete technical documentation (i.e., instructions and user manuals). At the time of this report's creation, WHO technical specifications were not available to compare this type of portable breathing and oxygen delivery apparatus.

Regulatory

Pre-market assessment	Proceed
Post-market assessment	Proceed with caution
Quality system assessment	Proceed
Security	Proceed

Pre-market: It has received CE certification. The manufacturers declared that they had conducted the design verification and validation of the product but did not submit these documentations. Consequently, full premarket assessments could not be conducted to ensure the safety and performance of the product.

Post-market: The manufacturers declared that they had the post-market documentation but did not submit the post-market surveillance and vigilance documentation. According to the submission, there have been no recalls or adverse events have been reported. Nevertheless, it is considered good regulatory practice to establish the complete post-marketing system before introducing the product to the market.

Quality management system (QMS): The manufacturing site is certified to ISO13485:2016.

Security: Introduction of this technology would not lead to biosecurity or cybersecurity risks. The manufacturer did not submit risk management systems documentation essential to ensure the safety and performance of the device.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	!	✓
Safety	→	
Economy	−	
Organizational	!	
Legal	!	
Social	→	✓
Ethical	→	✓
Green environment	!	

This innovation uses a re-breathing technique and consumes much less oxygen than free-flowing oxygen treatment. In low-resource settings, where oxygen sources are limited, it can help with more judicious use of oxygen and greater accessibility.

Clinical evaluation, test reports, and a CE mark showcase the device's medical performance. However, peer-reviewed evidence is missing to assess its feasibility in LMICs. The innovation has a good safety profile, validated by test reports and risk assessments according to ISO 14971.

The overall usability of the device is acceptable, according to the provided report. An ultrasonic cleaner with adequate capacity for cleaning the FIDO house and a SpO2 oximeter should be used, if available in the facility. The innovation is subjected to routine maintenance. Additional costs and downtime should be expected if the device is to be sent to the innovator's site abroad.

The cost of the device without any accessories amounts to 2700 EUR, which may be too high for LMICs, while the cost of consumables is also not negligible. A 0.10 EUR cost reduction per minute of treatment compared to the standard of care is claimed; however, this is calculated by only taking into consideration only some consumables and oxygen cylinders purchased in a high-income country.

Technology readiness level 9

Technology evidence assessment Recommend with caution

Health technology management

Durability
Ease of Use
Ease of maintenance
Environmental conditions
Affordability
Local access to technical support
Ease of cleaning
Infrastructure requirements

Health-care delivery platform

The Mirola Fido is a portable, mechanical oxygen rebreathing system that generates warm return air to the patient at ~33°C and provides humid air at less than 95% while maximizing available oxygen. It is only meant to be used in patients weighing more than 40 kg. Durability, biocompatibility, usability, and chemical resistance testing have been conducted. Cleaning the system, recommended every three months or every 200 uses, requires an ultrasonic cleaner. Mirola advises against local maintenance and instead recommends annual service by the manufacturer or associated approved distributors. No local commercial teams are currently available in LMICs to provide this service; Mirola has, however, committed to the development of commercial teams and replacement part availability in Algeria and the Democratic Republic of the Congo.

The FIDO system involves high initial capital investment and ongoing operational costs, primarily due to its reliance on single-use components; each use of the system requires a new set of items, including an oxygen bottle, breathing mask, biofilter, and cartridge, the total cost of which is 37 euros per use. Given their single-use nature, cost, and the need for frequent replacements, health-care facilities will face challenges in maintaining an adequate stock of these components to effectively use the FIDO effectively The current absence of local commercial teams in LMICs also indicates that facilities might incur extra costs, delays, and logistical complexities in procuring these items. The Mirola FIDO system is an innovative solution that would maximize the delivery of comfortable oxygen therapy, but the system's high cost and manufacturer-specific maintenance requirements limits its usefulness.

Intellectual property and local production

Technology transferability
Open source/ access
Local production

Intellectual property: The technology is protected by patents, trademarks, and copyrights. The use of all intellectual property will require clearance.

Local production: The device has a compliant manufacturing process. The technology has a moderate business case for semi-knocked-down manufacture. Some of the manufacturing know-how is likely to be with manufacturing partners. End-to-end manufacture is highly import-dependent and requires a comparatively high level of technical and quality control expertise, and related infrastructure. The device can be considered for local production, with an anticipation for low volumes until the technology is widely accepted in the region. Moderate cost reductions can be achieved through local production.

Commercially available
Minor update

Bedside newborn phototherapy

Commercial information

Model: Firefly
Development stage: Commercially available
Year published in compendium: 2011-2012

Updates:

Regulatory status: CE Mark, CFS
Energy requirements: Optional 2h internal battery backup available
List price (USD): 1500 (battery backup: 100 USD)
Currently sold: Globally except Australia, Canada, Japan, USA
Number of units distributed: 1500+

Bubble CPAP with built-in pulse oximeter

Commercial information

Model: Dolphin
Development stage: Commercially available
Year published in compendium: 2016-2017

Updates:

Regulatory status: CE Mark, CFS
Energy requirements:100-230V AC, 2h battery backup (excluding heat and humidity)
List price: from 3250 USD
Currently sold: Globally except Australia, Canada, Japan, USA
Number of units distributed: 1500+
In UN catalog: Yes, S0004057

Fetal monitor – wireless mobile

Commercial information

Model: Fetal Monitor iCTG
Development stage: Commercially available
Year published in compendium: 2022

Updates:

Lifetime: 5 years
Energy requirements: 10 hour usage for 1 hour charge with AC 110-250V rechargeable battery
Currently marketed in: Japan, Southeast Asia, Asia, Middle East, North Africa, and Brazil
Usability has been improved for the following items:

- Can be used for twins by adding an FHR transducer (optional) for single births. An optional SPO2 meter can be attached to monitor the mother's heartbeat at the same time.
- A single charge provides approximately 10 hours of transducer operation. The addition of an optional FHR transducer enables even longer monitoring and can also be used during delivery.
- An alarm function has been added to the iCTG app to warn of bradycardia and tachycardia in the foetal heartbeat.
- The device can now be washed with running water from a tap.

** This assessment was initiated November 2023

Commercially available
Minor update

2024

Heart rate meter for newborn

Commercial information

Model: NeoBeat and NeoBeat Mini
Development stage: Commercially available
Year published in compendium: 2021

Updates:

NeoBeat is available in two sizes:

NeoBeat: intended for use on newborns weighing approximately 1.5 – 5 kg.

NeoBeat Mini: Intended for use on newborns weighing approximately 0.8 – 2 kg

List price: The 2023 price for NeoBeat and NeoBeat Mini is 190 USD each to countries eligible for the not-for-profit pricing (https://tinyurl.com/ycx62jp5)

Currently marketed in: NeoBeat & NeoBeat Mini can be purchased to countries eligible for not-for profit pricing by Laerdal Global Health (https://tinyurl.com/ycx62jp5)

Shelf life: 3 years

Setting: Delivery and operating room

Product description as supplied by Laerdal:

NeoBeat is a reusable measurement device using dry electrode technology providing an ECG-based heart rate. ECG methodology is suggested by ILCOR 2022 guidelines as the reasonable method for heart rate assessment of a newborn infant requiring resuscitation in the delivery room, when resources permit. The hands-free device is easy-to-use and provides a digital display of the newborn heart rate in real-time.

User instruction as supplied by Laerdal:

NeoBeat is applied directly onto the newborn's wet torso, and rapidly provides an objective display of the heart rate. It is wireless and does not require single-use adhesive electrodes or any other consumables. Continuous measurement of the heart rate is intended to have a positive impact on early newborn assessment.

Phototherapy for jaundice

Commercial information

Model: Colibri
Development stage: Commercially available
Year published in compendium: 2016-2017

Updates:

Regulatory status: CE Mark, CFS
Energy requirements: Optional 2h internal battery backup available
List price (USD): 950 (battery backup: 100 USD)
Currently sold: Globally except Australia, Canada, Japan, USA
Number of units distributed: 1500+

Commercially available
Minor update

Ventilator for low oxygen inlet pressure

Commercial information

Model: Impala
Development stage: Commercially available
Year published in compendium: 2021

Updates:

Energy requirements: AC power supply (2h internal battery backup available)
Reference price (USD): From 3250 onwards
Year of commercialization: 2018
Number of units distributed: 1001-10 000
Regulatory status and standards compliance: CE Mark, ISO 13485, CFS
Currently sold: Globally, except US, Canada, Australia, Japan
In UN catalogue: Yes - S0004057 (https://supply.unicef.org/s0004057.html)

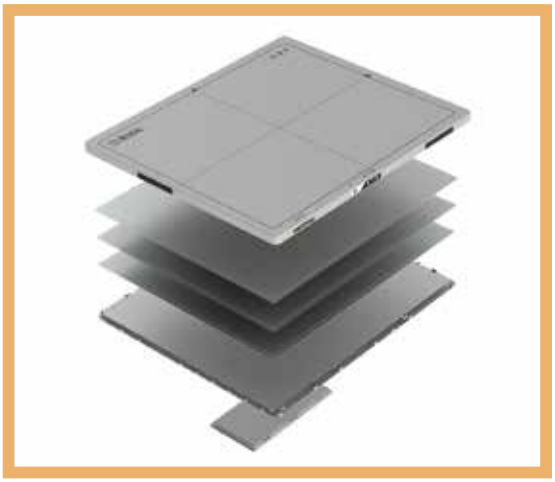
X-ray detector, dual energy, portable

Commercial information

Model: Reveal 35°C Flat Panel Detector
Development stage: Commercially available
Year published in compendium: 2021

Updates:

List price (USD): 50 000



2024

5. Technologies not listed in the Compendium

Out of 225 submissions received, 63 were complete and relevant, one was withdrawn, thus 62 were assessed. Technologies not listed in the Compedium include those that are not selected, rejected and withdrawn technologies. The assessment reports, which are not included either, were sent to the innovators to provide confidential feedback intended to contribute to improvement of the technology.

Submissions that are not selected

	Generic name	Company or affiliation	Brand or model	Country making submission
1	**Anti-fogging and cleaning components for endoscope scopes by heating**	Daiei Co., Ltd	Lapa hot	Japan
2	**Automatic bag valve mask machine**	Dar-es-Salaam Institute of Technology		United Republic of Tanzania
3	**Capnograph**	Lifebox Foundation Inc	Smile Train-Lifebox. SPLF-SWTY-PSP	China
4	**Cardiorespiratory monitoring system**	Medipines	AGM100	USA
5	**Continuous positive airway pressure**	Phoenix Medical Systems Pvt Ltd	Phoenix Neovent	India
6	**COVID-19 RT-PCR Kit**	Bangladesh Reference Institute for Chemical Measurements	BRiCM 16-031522-1820	Bangladesh
7	**Creatinine/eGFR meter**	Nova Biomedical	Nova Max Pro Creatinine/eGFR Meter	USA
8	**Direct selective laser trabeculoplasty**	BELKIN Vision	DSLT Eagle	Israel
9	**Early genetic test**	Genomelink		USA
10	**Eye Tracking Cognitive Assessment**	Ai-BrainScience Inc	-	Japan
11	**Health data mobility system**	VitaPass	VitaPass	USA
12	**Heart rate monitor**	Ernest Cook Ultrasound Research & Education Institute	-	Uganda
13	**Infant incubator**	MediCradle Foundation	MediCradle Incubator	USA
14	**Infrared thermography interpretive software**	NIRAMAI Health Analytix Pvt Ltd	Niramai Thermalytix	India
15	**Innovative monochromatic X-ray source for high quality and low dose medical imaging**	Massachusetts General Hospital	STARLIGHT G2eX90	USA

	Generic name	Company or affiliation	Brand or model	Country making submission
16	**Integrated mental health platform, distributed ledger technology - AI - IoT**	Quantum Brain Research Institute	KATLAS HealthNET	Estonia
17	**Maternity health digital solution**	SOIK Corporation Ltd	SPAQ	Japan
18	**Mechanical ventilator**	Pontificia Universidad Católica del Perú	Masi	Peru
19	**Medical care application**	Grenilla	Grenilla	Malawi
20	**Mobile application for front-line worker resilience and well-being in low-resource settings**	Dimagi	CommCare/ Wellme	USA
21	**Neonatal jaundice screening tool (icterometer) with lighting indicator**	Little Sparrows technologies	Bili-ruler	USA
22	**Neonatal skin maturity optical reader**	Birthtech Dispositivos para a Saúde Lda	Preemie Test. GA01	Brazil
23	**Nucleic acid testing apparatuses – rapid point-of-care tests**	Identify Sensors Biologics	Identify Sensors Biologics/ Check4 System	USA
24	**Orthogonal phase encoding reduction of artefacts**	Meditec.srl	OPERA 1	Italy
25	**Portable autorefractor**	PlenOptika	PlenOptika/ QuickSee Free	Spain
26	**Pressurized steam disinfection chamber**	Ideal Flow Control Pvt. Ltd.	CoAyurSteam	India
27	**Real-time continuous glucose monitoring**	Ambrosia Systems Inc	Waterproof NightRider BluCon and FreeStyle Libre Pro Sensors	USA
28	**Reusable insulin injection device**	GO-Pen ApS	GO-PEN	Denmark
29	**SmartBio lab**	COVMATIC	COVMATIC. OpenTrons OT2, Biorad CFX	Italy
30	**Surgical assist male circumcision device**	Unicirc Pty. Ltd.	Unicirc/ UC0	South Africa
31	**Telemedicine gateway solution**	Diagnext	Telemedicine Gateway v3.0	Brazil
32	**Urinary branched-cahin amino acid supplementation quantification kit**	Innov Biotech	IDIR SKC-PDT-001	France
33	**Viral transport media**	Bangladesh Reference Institute for Chemical Measurements	BRiCM VTM	Bangladesh

Updates that are not selected

These technologies were listed in previous versions of the Compendium, and the innovators submitted updated evidence for re-assessment. The results of the assessments were similar to those in the previously published full profiles, or the evidence provided was insufficient to change the assessment.

	Generic name	Company/ affiliation	Brand/ Model	Country making submission
34	Clinical management support software	THINKMD	THINKMD 5.0	USA
35	EURS Emergency use resuscitator	Ligand Innovation Global	LifeAir / VitaCaeli G1	Canada
36	Portable breast examination device	UE LifeSciences	iBreastExam Gen II iBE1	USA
37	Portable automated ultrasound	Bloom Standard	Bloom Standard/ EVA RAPIDscan	USA
38	X-ray detector, dual energy, portable[a]	KA imaging	Reveal 35°C Flat Panel Detector	Canada

[a] This update was not listed with a full assessment but was included in the minor updates.

Submissions that were rejected

These technologies were rejected because the documentation in the submission did not conform to WHO document requirements.

	Generic name	Company/ affiliation	Brand/ Model	Country making submission
39	12 Channel Electrocardiograph Machine and Electrocardiograph Analysis Software	Wellnest Tech	Wellnest12L	India

Submissions that were withdrawn

	Generic name	Company or affiliation	Brand or model	Country making submission
40	10L Oxygen Concentrator for Low Resource Settings[a]	Oxus America	Oxus 10	USA
41	Bubble CPAP System[b]	Vayu Global Health Innovations	Vayu CPAP	Kenya
42	Xray imaging service for easy access to radiology diagnostics[b]	Open Diagnostics	Pristem Cristalix-T1	Switzerland

[a] Withdrawn by innovator before the assessment was initiated
[b] Withdrawn by innovator after the assessment was completed and shared with the innovator

6. Discussion and conclusion

The WHO Compendium of Innovative Health Technologies for low-resource settings provides evidence-based information on technologies that meet demands for appropriate, accessible, affordable, effective, safe health solutions in resource-constrained settings. This volume contains comprehensive assessments of 20 health technologies submitted to WHO for the first time and eight updates of technologies in previous volumes. It covers a variety of technologies, including medical equipment, diagnostics (both in vitro and non-in vitro tests, some aided by software) training devices and other solutions to enhance health-care delivery in low-resource settings. The technologies address critical health priorities, including NCDs, antimicrobial resistance and maternal and newborn health.

The 2024 Compendium contains 28 technologies from 14 countries – Canada, China, Denmark, France, India, Japan, New Zealand, Norway, Republic of Korea, Sweden, Switzerland, United Republic of Tanzania, USA and Viet Nam – three of which are LMICs. And eleven of the technologies can be use in the management of NCDs: autologous blood transfusion device, dry format card for ABO blood groups and rhesus factor typing point-of-care test, patient monitoring system, smart eye camera attached to a smartphone, smartphone application for blood pressure monitoring, ultrasound imaging system, digital microscope, laptop cystoscope, smart eye camera fundas model, electroencephalography instrument/device, and passive, contact-free, continuous vital sign monitoring.

A refined method and rigorous assessment were used to provide objective, useful information to readers, including decision-makers in those settings. Multidisciplinary assessments were conducted by a team of experts versed in various domains, ensuring comprehensive evaluation of each technology's suitability. Feedback from previous reviewers and consultations with the STAG MEDEV further improved the method, reflecting the importance of a multidisciplinary assessment.

As decision-makers often lack access to comprehensive assessments of innovative technologies, the Compendium bridges this gap by listing technologies that are specifically designed for low-resource health environments. This empowers stakeholders to make evidence-informed decisions, leading to adoption of technologies that enhance the quality of health care, eventually improving health outcomes in their own local setting.

The information provided in the Compendium assists potential users who are considering adoption by determining the suitability of a technology for their context. Factors such as effectiveness, safety, regulatory compliance, ease of maintenance and of use were considered. Technologies that were assessed but were not included in the Compendium are listed above. The assessment reports were sent to submitters to provide information for improving the technologies.

The Compendium thus serves to identify a wide range of innovative health technologies that address critical needs in low-resource settings. We anticipate that the Compendium will facilitate access to technologies, leading to better quality of care, service and eventually health outcomes (14,15). By listing a range of innovative health technologies, we encourage collaboration among stakeholders to find solutions suitable for low-resource settings, thereby contributing to advancement of health-care equity through increased access to health technologies.

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